NUCLEAR MANAGEMENT AND RESOURCES COUNCIL

1776 Eye Street, N.W. • Suite 300 • Washington, DC 20006-2496
(202) 872-1280

July 18, 1990

Mr. Edward L. Jordan, Chairman
Committee to Review Generic Requirements
U.S. Nuclear Regulatory Commission
Mail Stop 3701
Washington, D.C. 20555

Dear Mr. Jordan:

NUMARC has met numerous times over the past two years with members of the NRC Staff in seeking a consensus on the resolution of Generic Issue B-56, Diesel Generator Reliability. The Staff made public the B-56 resolution package that was submitted to you this past June. Our review of this package raised a number of concerns regarding the Staff's approach to the resolution of this issue. We have enclosed a detailed set of comments that address specific items in the resolution package for CRGR information. We would also like to take this opportunity to clarify our position on this issue so that you and your committee will be fully apprised of our intent and actions taken by industry.

We believe that there are three elements that together provide the basis for closure of the B-56 issue. The first is the recognition of industry performance with regard to the reliability of emergency diesel generators (EDGs) over the past several years. Since 1983, data compiled by EPRI and INPO establish that the industry average reliability has been above 0.98. This data has been acknowledged and accepted by the Staff. Recognizing that the intended goal of the B-56 issue (as well as the Station Blackout rule) was to achieve 0.95 reliability per EDG demand, it is evident that industry performance has not only achieved, but surpassed this goal.

The second element that forms the basis for closure of B-56 is the establishment of consensus trigger values to monitor nuclear unit EDG target reliability. Utilities were required to select either a 0.95 or 0.975 target reliability as part of their coping assessments, and their selections were docketed through their SBO rule responses to NRC. In supplemental responses to NRC, utilities acknowledged their commitment to maintain the chosen reliability. The trigger values are the main subject of Industry Initiative 5A, which was approved by the NUMARC Board of Directors on March 7, 1990. This initiative commits all nuclear utilities to utilize these trigger values to monitor their selected EDG target reliability. The Staff had previously agreed to the trigger values (ref. RG 1.9, Rev. 3, 11/28/89 draft, Section C.3.4), which provide a uniform method to oversee emergency diesel generator performance.



9405160083

Attachment 4
to Enclosure 3

The third element that provides the basis for closure of B-56 is revision 1 to NUMARC 87-00, Appendix D, "EDG Reliability Program". The revised Appendix D has been distributed to all NUMARC Members. Appendix D provides a method of monitoring and maintaining EDG target reliabilities. Appendix D focuses on effectively responding to individual EDG failures and taking appropriate remedial actions when trigger values are exceeded. The main points of the guidance provided in Appendix D have essentially been duplicated in the Staff's proposed revision 3 to Regulatory Guide 1.9 (ref. Sections C.2.1, C.3.3, C.3.4, C.4 and C.5).

One other point that we wish to clarify is our development and distribution of the Appendix D Topical Report. This Topical Report contains detailed information on EDG program elements, root cause analysis, and quality improvement techniques. It was provided to all NUMARC Members for their information and use at the same time that Appendix D was distributed. Much of the information in the Topical Report was contained in a previous version of Appendix D that the CRGR reviewed last October. There were several reasons for separating this information into the Topical Report. First, the information was viewed as too prescriptive to be included with the guidance in Appendix D, as this type of prescriptiveness was unwarranted in light of the high industry average reliability. Secondly, it was our belief that the NRC would focus on performance consistent with positions expressed by the Commission, rather than programs. Thirdly, there were serious concerns raised by utility reviewers that this information would be used in the inspection process by NRC. We believe that inspection of utility EDG programs absent declining EDG performance (i.e. exceeding the trigger values) would be a poor use of both utility and NRC resources. For these reasons, the Topical Report was not included in our submittal to the Staff.

We now observe in the B-56 resolution package that the Staff has included a section in the proposed revision 3 to Regulatory Guide 1.9 that details specific program elements. Additionally, the package contains a proposed generic letter that requests utilities to submit statements, pursuant to 10 CFR § 50.54(f), regarding their intent to implement the regulatory guide positions. We strongly oppose these actions and believe them to be unnecessary and unwarranted in light of the established industry performance and the NUMARC actions taken to address and resolve the B-56 issue.

In conclusion, we believe that industry actions addressing resolution of the B-56 issue provide the NRC Staff with the following:

1. A docketed commitment to maintain the chosen target reliability of 0.95 or 0.975;

2. A commitment to a standard set of trigger values, acceptable to NRC, from which to monitor EDG target reliability;

3. Information relative to individual EDG failures and associated corrective actions;

4. Information relative to the combination of individual failures as they relate to plant unit performance and reliability, and

5. Information relative to comprehensive programmatic improvements resulting from the assessments following double trigger exceedence.

We believe that Generic Issue B-56 has been satisfactorily resolved by the industry without the need for regulatory action. We ask that CRGR give our position due consideration and hope that the enclosed comments will be useful at the upcoming CRGR meeting on the B-56 issue. Please contact me or Alex Marion should you have any questions.

Sincerely,

William H. Rasin
Director, Technical Division

AM/ARP/
Enclosure

cc: T. Murley, NRC
E. Beckjord, NRC
A. Thadani, NRC
W. Minners, NRC

Enclosure 1

ASSESSMENT OF THE NRC'S RESOLUTION PACKAGE FOR CLOSURE OF GENERIC ISSUE B-56

The comments and discussion on aspects of this package follow the order of the documents contained therein. References to specific page numbers, paragraphs and line items are made to facilitate quick reference where appropriate.

Transmittal Cover Letter - E. Beckjord to E. L. Jordan, CRGR Chairman

Item 2 of the cover letter correctly states that the Topical Report was not submitted to the NRC. However, there is a statement that the report will only be provided to utilities as needed. Although our actions in this regard were discussed with cognizant NRC Staff, we believe it appropriate to clarify our reasoning for not forwarding the Topical Report to the NRC and emphasize that the topical was indeed issued to industry. Not submitting the topical to the NRC was recommended by the Station Blackout Working Group and based upon our belief that the NRC would focus upon performance consistent with positions expressed by the Commission, rather than programs. The Working Group and NUMARC recognized that proven industry average EDG reliability of 0.98 since 1983 exceeds the B-56 and SBO Rule target goal of 0.95. Additionally, as part of the SBO rule response, utilities were required to choose a target reliability of 0.95 or 0.975. Utilities have docketed their understanding that the chosen target is to be monitored and maintained. Consistent with this, the NUMARC Board of Directors approved an industry initiative that provides a mechanism for monitoring and maintaining EDG reliability. All of these efforts have been acknowledged by the NRC.

We believe the Generic Issue B-56 is resolved. Furthermore, we believe no benefit can be gained by a focus on a program for an issue that can be considered resolved based upon current industry performance and industry actions. Absent declining performance relative to maintaining the chosen target reliability, we believe expenditure of resources to inspect reliability programs is unnecessary.

Item 3 of the letter correctly indicates the NUMARC transmittal to the NRC does not "commit" the industry to implementation of Initiative 5A and Appendix D. This, of course, is a valid point relative to a docketed regulatory commitment. As indicated in NUMARC's May 3, 1990 transmittal, Initiative 5A provides the approved mechanism

to be used by all utilities for monitoring EDG target reliability. The revised Appendix D provides guidance on utilization of the consensus trigger values and taking remedial actions to restore performance when the trigger values are exceeded. It should be recognized that the NUMARC Board of Director's approval does constitute a commitment by industry to Initiative 5A that provides a acknowledged generic mechanism for consistent application across the industry. The Appendix D guidance document will be incorporated into a revision of NUMARC 87-00, Guidelines and Technical Bases for NUMARC Initiatives Addressing Station Blackout at Light Water Reactors that will be published this summer. Appendix D, as an integral part of the NUMARC 87-00 document, should be treated as similar guidance since it is recognized that there are other methods for maintaining the chosen EDG reliability targets that are acceptable to both the NRC and industry.

Based upon the above a request pursuant to 10 CFR § 50.54(f) is not appropriate. Utility licensee commitments to the reliability target have been made as part of the SBO rule responses. The industry commitment to Initiative 5A is complete. The supporting Appendix D guidance has been issued to all utilities. Industry performance is above the 0.95 reliability goal intended by Generic Issue B-56. The totality of these actions indicate that such a request is not required.

Enclosure A - Responses to CRGR Comments

Comment 1 - Refer to the previous discussion relative to the reduced scope of Appendix D, ie., excluding the Topical Report. We believe that adoption of Appendix D by reference is supportable based on the NRC Staff acceptance of industry performance, Initiative 5A and the current version of Appendix D.

Comment 2 - The extent to which NUMARC agrees with a consensus industry approach is discussed above.

Comment 3 - The commitment by the nuclear utility industry through NUMARC in the form of the initiative process is complete by action taken by the NUMARC Board of Directors in approving Initiative 5A. Commitments by individual licensees to a target reliability currently exist. Therefore, citing 10 CFR § 50.54(f) is not necessary.

Comment 4 - We do not concur with the Staff's backfit analysis. Refer to comments on Enclosures C and D.

Comment 5 - The conclusions relative to substantial safety improvement and cost justifications are inappropriate since the intended reliability goal for Generic Issue B-56 has already been achieved and exceeded. Therefore, NUMARC does not concur with the Staff's consideration that the B-56 issue is "...an outstanding safety issue related to USI A-44...". Because of the established performance relative to EDG reliability and commitments related to the Station Blackout rule, we believe the B-56 issue is resolved.

Comment 7 - The Staff response to this comment supports our concerns that the intent is to inspect programs independent of actual performance and currently docketed licensee commitments. As stated previously, we believe this an inappropriate use of industry and unnecessary use of NRC resources to assess compliance to what is currently a non-issue that in effect deters already limited resources from more important areas of acknowledged safety benefit or improvement.

Enclosure B - Regulatory Guide 1.9, 6/14/90

[References made relative to changes in previous NRC Staff positions refer to the 11/28/89 draft of the proposed regulatory guide.]

DISCUSSION, p. 5, 2nd paragraph from the bottom, 2nd sentence -- Actions and guidance necessary to maintain and monitor EDG reliability are currently in place. Improvement of reliability has already been achieved without the need for prescriptive guidance on program content and structure.

p. 6, first para. -- The minimum reliability goals intended by RG1.155 and Generic Issue B-56 have been achieved. As discussed earlier, maintaining and monitoring EDG reliability can be accomplished without mandating a prescriptive program.

2nd para. -- This discussion relative to the new Standard Technical Specifications (STS) should be clarified as it is not clear whether the proposed regulatory positions expressed in this guide can be effected in TS at this time or until some time after NRC endorsement of the STS. Additionally, we have been working with the NRC Staff for the past two years in trying to achieve resolution. We believe that industry actions have established an effective resolution. The STS should not present another opportunity, absent generic performance based concerns, to revisit the positions that had been thoroughly reviewed and concurred with.

Agree mostly by Brid

3rd para. -- We believe this paragraph contains appropriate NRC guidance since it clearly states that the NRC Staff "...finds it (revised Appendix D) acceptable for monitoring and maintaining EDG reliability levels." We recommend this or a similar statement be articulated as a regulatory position. Any additional duplication of Initiative 5A or NUMARC 87-00 Appendix D content is unecessary.

Regulatory Position (RP) C.1.5 -- The previous draft of this revision , dated 11/28/89, identified RP C.1.5.2 relating to time rates for starting and loading being consistent with manufacturer's recommendations. This position has been removed from this draft. We believe the previous position should be reinstated as it is consistent with the intent of GL 84-15.

RP C.2.2.1, p. 12 -- Previous drafts of this document referred to this as a Start-Test. Characterizing it now as "Slow-Start Test" may create confusion in interpreting the difference between this test and the remaining tests. We believe that this regulatory guide should be consistent with the intent of GL 84-15 and current state of knowledge of emergency diesel generators. The previous characterization of a generic type of "start test" is well understood.

RP C.2.2.2 -- Same comment as with RP C.2.2.1 but within the context of load run.

RP C.2.2.3, p. 13 -- This test was previously identified as a Fast Start Test and the intent understood. The proposed change appears to affect the title only since the test description for this "Fast-Start and Load Test" is the same as before. It does not provide any guidance relating to loading of the EDG. (The load run test is addressed by RP C.2.2.2.) The fast start test is intended to bring the EDG to the required voltage and frequency within specified time limits as described. It was our understanding that if a utility wishes to conduct the fast start test at a six-month interval, then it replaces that month's normally scheduled start test. However, a load run test would follow in eiother case as part of the normal monthly surveillance.

RP C.2.2.4 -- The addition of "...and energizes permanently connected loads..." was added to a previously understood test description. The inclusion of permanently connected loads appears unjustified in that it precludes load shedding and sequencing currently designed for in simulating SIAS and LOOP.

RP C.2.2.6 -- Same comment as on RP C.2.2.4 regarding the permanently connected loads.

RP C.2.2.8 -- Refer to previous comments and earlier drafts that related to automatically sequenced loads. The Staff and NUMARC concurred with automatically sequenced loads as representative of the type necessary to demonstrate this test. This is a reversal in Staff position that now focuses on "...continuous rating...".

RP C.2.2.9 -- Similar comment as on RP C.2.2.8 wherein the Staff reversed a previous position and focuses on continuous rating.

RP C.2.2.12 -- The correct reference to the SIAS test is RP C.2.2.5.

RP C.2.3.1 -- This is a change in a previously understood Staff position that is now unclear and confusing. The appropriate tests to be conducted on a monthly basis are the start and load-run as described in RP C.2.2.1 and C.2.2.2, with the noted comments. The replacement of the normally scheduled start test by RP C.2.2.3, in effect a fast start test on a six month interval, is addressed by RP C.2.3.2.2, Six-Month Testing and should be discussed separately.

RP C.2.3.2.2 - We believe this six month test is unnecessary and inconsistent with the intent of GL 84-15. Comments have been previously provided to the Staff questioning the benefit of such a test given the increased stress and wear due to the fast starting and loading. NRC's research has also found that fast starting and loading is detrimental to EDGs. We believe continuing these types of tests on intervals less than refueling outages, i.e., six month basis, is counterproductive to safety in terms of equipment availability.

RP C.2.3.3 -- The title of this position, Corrective Action Testing, is somewhat confusing because the discussion of this position relates to an individual EDG exhibiting 4 failures out of the last 25 demands. We suggest the addition of Problem EDG to the title so that it reads Corrective Action Testing-Problem EDG. The process of performing corrective actions in response to individual EDG failures is currently in place across the industry without the mandate of a prescriptive "...nuclear unit EDG reliability program...". 10CFR50 Appendix B, Criterion XVI, Corrective Action, and other existing regulations provide appropriate and sufficient guidance to licensees.

RP C.3, pp. 16-19, ff. -- We believe the entire section can be deleted as it essentially duplicates what is in NUMARC 87-00 Appendix D that has been acknowledged by the NRC Staff and issued to industry. There are, however, differences in the Staff version that we believe will lead to confusion.

We believe the Staff acknowledgement as stated in the Discussion, p. 6, 3rd para. is appropriate and sufficient.

RP C.4, pp. 19-20, ff. -- We believe this section should be deleted in it's entirety as it duplicates what is called for in the revision to NUMARC 87-00 Appendix D.

RP C.5, p. 20 -- We have received the revision to this position that was issued July 10, 1990. The previous position noted in the 6/14/90 draft relative to reporting EDG failures is clear, understood and more importantly focuses on a fundamental element - individual EDG failures. The proposed change relating to reporting the problem EDG is not necessary. Current regulations require reporting of the individual failures. The imposition of this additional report does not bring to the NRC any additional information relative to EDG failures that has not been previously submitted on an individual failure report.

RP C.6, pp. 20-26, ff. -- We believe this entire section regarding a reliability program is not necessary and should be deleted from this regulatory guide. As stated previously, we see no benefit or improvement in safety by conducting inspections of utility programs independent of performance. The existing technical specifications, regulations and reporting criteria require utilities to apprise the NRC regional and headquarters personnel of individual EDG failures, corrective actions, etc.

The revision to NUMARC 87-00 Appendix D focuses on monitoring EDG performance relative to the trigger values and taking appropriate remedial actions when these values are exceeded. Additionally, the guidance focuses on establishing a trend or pattern of individual failures by a review of the applicable past failures, evaluating the corrective maintenance tracking history and assessing specific program elements that may be implicated, e.g., training, maintenance, etc. These actions are called for when a single trigger is exceeded. However, upon exceeding both the 50 and 100 demand triggers, the guidance calls for a comprehensive review of the reliability program. The Topical Report that was forwarded to all utilities provides information to support such a review activity that includes recognized analytical and quality improvement techniques.

In conclusion, we believe industry actions addressing resolution of this issue provide the NRC Staff with the following:

1) docketed commitment to maintain the chosen target reliability of 0.95 or 0.975,

2) commitment via Initiative 5A to a standard set of trigger values,

3) information relative to individual EDG failures, and associated corrective actions,

4) information relative to the combination of individual failures as they relate to plant unit performance and reliability, and

5) information relative to comprehensive programmatic improvements resulting from the assessments following double trigger exceedence.

Section D, p. 26 -- The Staff intentions relative to select positions of the regulatory guide to review monitoring EDG reliability levels, record keeping, reporting of failures and reliability programs is unnecessary. Refer to the detailed comments noted to the related regulatory positions. We believe the Staff should review utility corrective actions in response to individual EDG failures as is currently being done within the current regulations. We also believe the Staff should monitor utility performance in maintaining the EDG reliability trigger values and assess remedial actions in accordance with Appendix D or other means acceptable to the NRC.

Table 2 - The previous comments relative to the RP C.2.2.3 and C.2.3.2.2 apply in that we believe this type of fast start and fast load test should not be on an interval less than that of current refueling outages of 18 or 24 months.

Tables 3, 4A and 5 -- These are offered in our Topical Report as examples of surveillance activities as information only. These examples do not apply to all manufacturer's EDG or utility activities. Given the Staff's intent to inspect programs, we believe these lists will be used by inspectors for compliance as requirements. Accordingly, we request they be removed from the regulatory guide as the listed information does not relate to maintaining and monitoring EDG target reliability.

Figure 1 -- This can be deleted as it duplicates what is in the revision to NUMARC 87-00 Appendix D that has been issued to utilities.

ENCLOSURE C - PROPOSED GENERIC LETTER

We do not believe that the proposed revision to Regulatory Guide 1.9 offers a technical resolution to Generic Issue B-56. As previously stated, we believe this issue is currently resolved based upon the acknowledged industry performance relative to EDG reliability, Initiative 5A and the revised Appendix D to NUMARC 87-00. The issue can be closed by issuance of a generic letter that acknowledges Appendix D as providing guidance for maintaining and monitoring EDG reliability.

As stated previously, there is no basis for invoking 10 CFR § 50.54(f).

With regard to submitting TS change requests, the language in the 2nd paragraph, second page, suggests implementation of Initiative 5A, Appendix D, Regulatory Guide 1.9 RP C.3, C.4, C.5 and C.6 prior to a submittal. Since RP C.3 through C.5 essentially duplicate that which is contained in Initiative 5A and Appendix D, we do not understand the benefit of requesting compliance and commitment to redundant references. Utilities are committed to Initiative 5A and will use the guidance contained in Appendix D, as previously discussed. Appropriate remedial action will be taken by utilities when the performance and reliability trigger values are exceeded.

Furthermore, the rationale for linking the line-item TS improvements identified in RP C.2 to implementation of programmatic requirements is unclear and inconsistent. The current revision 2 of Regulatory Guide 1.9 has somewhat similar testing requirements that are not coupled to a programmatic commitment, but currently allowed in TS.

We do not concur with the determination that a substantial increase in overall protection of the public health and safety is achieved by the regulatory guide positions. Industry through the efforts of EPRI, INPO and NUMARC has improved EDG availability and reliability. The results of these efforts are published in EPRI NSAC-108, reflected in the Industry-wide Plant Performance Indicator Program (PPIP) managed by INPO, NUMARC commitment to Initiative 5A, and the publication of the revision to NUMARC 87-00 Appendix D. The EPRI report and the PPIP data indicate that since 1983 the industry average EDG reliability exceeds the NRC's desired goal of 0.95. The NRC Staff acknowledges the common set of rules and definitions established by the PPIP, and the

mechanism for monitoring and maintaining EDG reliability is currently in place via Initiative 5A and Appendix D. Since these are currently in place then the actions proposed by the NRC Staff in RP C.3 through C.6 are unnecessary. We recommend the NRC formalize their acknowledgement via generic letter since the industry actions and guidance are complete and in effect.

ENCLOSURE C.2 - GUIDANCE FOR THE PREPARATION OF LICENSE AMENDMENT REQUESTS, etc.

The guidance proposed by the Staff suggests that establishment of a program in accordance with the regulatory guide positions permits a reduction in accelerated testing frequency. We do not concur that the conditional requirement for a program is necessary in order to implement this reduction. This conditional requirement is unacceptable to industry because it is inconsistent with positions expressed by the Commission suggesting a realistic focus on demonstrated performance rather than compliance to interpretive programs. Industry performance has been demonstrated and a mechanism is in place to maintain and monitor that performance. Furthermore, in our discussions with the Staff during the past two years, we expressed our belief that any form of accelerated testing is contrary to the fundamental tenant of reliability focused activities. However, in the spirit of cooperation to achieve concomitant resolution of Generic Issue B-56 with the Staff, we concurred with the proposed reduction in accelerated testing and incorporated it into Initiative 5A and Appendix D. We can only express our disappointment that the Staff is yet unwilling to allow industry to pursue self-improvements that have an established performance based approach.

ENCLOSURE D - BACKFIT ANALYSIS

We do not believe the Staff has satisfied the backfitting rule requirements, 10 CFR § 50.109. Because the proposed B-56 resolution involves a backfit i.e., implementation of a specific reliability program, a separate backfitting justification is required. Our review of the regulatory analysis for USI A-44 as contained in the referenced NUREG-1109 document reveals that the Staff did not separately quantify the risk reduction or evaluate expected costs to industry associated with the implementation of EDG reliability programs.

We believe that the Staff's reliance on 10 CFR § 50.54(f) as a mechanism to require utility licensees to provide statements of their intent to implement EDG reliability programs is inappropriate. By doing so, the NRC in essence

converts guidance contained in regulatory guide positions into regulatory requirements. Requirements should only be established by proper rulemaking procedures, which have not been followed in this case.

As stated previously, appropriate guidance on monitoring EDG reliability levels currently exists and has been acknowledged by the Staff.

Given that the desired reliability levels have been achieved, we question the need to expend additional industry and NRC resources to review current methods and practices for consistency with the regulatory guide positions.

The analysis acknowledges that utilities with operating plants have surveillance and maintenance programs in place that are currently applied to EDGs. Established industry performance and actions implemented by NUMARC show that current programs are effective.

The 7/5/90 revision to the resolution package suggests the Problem EDG condition impacts EDG maintenance and represents a deterioration of nuclear unit reliability. An assessment of the impact of a Problem EDG as it may relate to maintenance should be based upon the root cause of the experienced failures and the associated corrective actions. To conclude that such a condition generically represents an "..inability to correct failures..." is premature and inappropriate. Additionally, the Problem EDG, defined as an individual EDG experiencing 4 or more failures in the last 25 demands, presents an inadequate sample size to draw a statistically valid assessment of nuclear unit reliability.

7-25-90
Draft

RESPONSES TO NUMARC'S COMMENTS
ON RG 1.9, REV. 3

Pg 5, 2nd Paragraph (from bottom) - Retain

The Staff believes that a reliability program in conjunction with monitoring of EDG reliability should be implemented to assure that the minimum EDG reliability goals of selected for compliance with the SBO rule are acheived and maintained.

Pg 6, 1st Paragraph - Retain

A program is not being mandated. RG 1.9, Rev. 3 provides guidance for an EDG reliability program which supplements brief guidance provided in RG 1.155. The A-44 FRN stated : "The resolution of B-56 will provide specific guidance for the staff or industry to use to review the adequacy of diesel generator eliability programs consistant with the resolution of A-44."

Pg. 6, 2nd Paragraph - Delete

This paragraph will be deleted from the guide. The intent was to identify activities underway with NUMARC to arrive at mutually acceptable revisions to Standard Tech Specs.

Pg 6, 3rd Paragraph - Retain

Reference to NUMARC 87-00, Appendix D (5-2-90) has been made as appropriate throughout the guide. We feel some duplication of Initiative 5A and NUMARC 87-00 appendix "D" is necessary to make this guide as a "stand alone document" rather than scattering the guidance among too many documents.

Regulatory Position C.1.5 - Retain

The staff feels that requiring design features such as slow starting and slow loading will unnecessarily complicate EDG control circuitry even more. Moreover, the staff has made it very clear throughout the guide that for monthly tests the EDG should be slow started and loaded.

Regulatory Position C.2.2.1 - Change

The guide will be revised to re-title this position as "Start Test."

Attachment 5
to Enclosure 3

Regulatory Position C.2.2.2 - Change

The guide will be revised to re-title this position as "Load Run Test."

Regulatory Position C.2.2.3 - Change

This was a typographical error; RP C.2.2.3 will be re-titled: "Fast Start"

Regulatory Position C.2.2.4 - Retain

The intent of this position was simply misunderstood by NUMARC. There are some loads on the safety buses which are not shed on a loss-of-offsite power signal. Therefore, the staff requires that the EDG should have the capability to carry such loads when it is connected to the safety bus. Moreover, this RP is consistent with the new STS.

Regulatory Position C.2.2.6 - Retain

Same comment as on Regulatory Position C.2.2.4 regarding the permanently connected loads.

Regulatory Position C.2.2.8 - Retain

Testing the EDG at automatically sequenced loads will not include manually connectable loads. The staff believes that the full load rejection test should be conducted at loads that are connected to the safety bus at any given time (i.e. automatically sequenced and manually connectable loads). Moreover the Regulatory Position allows this test to be conducted at 95 to 100% of the EDG continuous rating.

Regulatory Position C.2.2.9 - Retain

Same comments as on Regulatory Position C.2.2.8 regarding testing of the EDG at the continuous rating.

Regulatory Position C.2.2.12 - Change

Reference to Regulatory Guide C.2.2.6 is correct. The guide will be revised to include Regulatory Positions C.2.2.5 and C.2.2.6.

Regulatory Position C.2.3.2.1 - Change

The staff believes NUMARC's reference to RP C.2.3.1 is a typographical error. Their comments appear to address RP C.3.2.1. The wording in RP C.3.2.1 correctly references the start and load definitions.

Regulatory Position C.2.3.2.2 - Retain

The staff notes that "all" EDG starts are "fast" starts as governed by the design and operation of a diesel engine. RP C.2.3.2.2 (the 6 month test) is designed to demonstrate starting from standby conditions and reaching valid voltage and frequency within Tech. Spec. limits. The "load-run" (which follows the start from standby condition) is identical to the monthly surveillance test. The RG further notes that this test may be substituted for the monthly test.

The staff believes NUMARC is re-focusing on past discussions related to the need for any tests related to large LOCA license requirements.

Regulatory Position C.2.3.3 - Title will be changed

This section will be re-titled "Corrective Action Testing - Problem EDG."

Regulatory Position C.3 (pp. 16-19) - Retain

The staff feels that incorporation of identical wording from NUMARC's Appendix D (5-2-90) into RG 1.9, Rev. 3 is a prudent thing to do in view of NUMARC's continuing changes and recently stated positions. This RG will provide regulatory guidance language for both reviewer and licensee to use.

Regulatory Positions C.4 - Retain

Same reason as noted above.

Regulatory Position C.5

The staff's revised reporting positions which reduces current reporting requirements (for those plants currently complying with RG 1.108 which report all failures) is a relaxation. For those plants that have no failure reporting requirements - this is a backfit.

Regulatory Position C.6 - Retain

The guidance for an EDG reliability program provided in RG 1.9, Rev. 3 defines the elements of an EDG reliability program which are identical to elements valid in NUMARC's Appendix D, and which also provides illustrative examples of proven considerations and practices employed by the industry. Section C.6 supplements guidance provided in RG 1.155.

It should also be noted that Section C.6 clearly recognizes (see pg. 20 of the RG) the effectiveness of existing programs and is not intended to replace or supplement such programs.

Further it should be noted that Sections C.6.2, C.6.3, C.6.4, C.6.5, C.6.6 and C.6.7 reflect guidance (in condensed form) currently found in NUMARC's typical Report which was not submitted. Therefore, the staff feels that prudence supports retaining the limited and general guidance in RG 1.9, Rev. 3.

SENT TO PDR ON 4/21/94

MATERIAL RELATED TO CRGR MEETING NO. 190
TO BE MADE PUBLICLY AVAILABLE

1. MEMO FOR J. TAYLOR FROM E. JORDAN DATED 9/14/90
SUBJECT: MINUTES OF CRGR MEETING NUMBER 190
INCLUDING THE FOLLOWING ENCLOSURES WHICH WERE NOT
PREVIOUSLY RELEASED:

a. ENC
A
PROPOSED Standard
on Quality Assurance

b.
PROPOSED Resolution

## ROUTING AND TRANSMITTAL SLIP

Date 4/21/94

| TO: (Name, office symbol, room number, building, Agency/Post) | Initials | Date |
|---|---|---|
| 1. BCS P1 37 | | |
| PDR | | |
| 2. | | |
| 3. | | |
| 4. | | |
| 5. | | |

| | | | |
|---|---|---|---|
| Action | | File | Note and Return |
| Approval | | For Clearance | Per Conversation |
| As Requested | | For Correction | Prepare Reply |
| Circulate | | For Your Information | See Me |
| Comment | | Investigate | Signature |
| Coordination | | Justify | |

REMARKS

This previous Central File material can now be made publicly available.

MATERIAL RELATED TO CAGR MEETING NO. 190

CC (LIST ONLY) JEAN RATAJE, PDR L STREET

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post) DENNIS ALLISON

Room No.—Bldg.

Phone No. 24148

5041-102

OPTIONAL FORM 41 (Rev. 7-76)
Prescribed by GSA
FPMR (41 CFR) 101-11.206

120046

SENT TO PDR ON 4/21/94

MATERIAL RELATED TO CRGR MEETING NO. 190
TO BE MADE PUBLICLY AVAILABLE

1. MEMO FOR J. TAYLOR FROM E. JORDAN DATED 9/14/90
SUBJECT: MINUTES OF CRGR MEETING NUMBER 190
INCLUDING THE FOLLOWING ENCLOSURES WHICH WERE NOT
PREVIOUSLY RELEASED:

a. ENCLOSURE 2
A SUMMARY OF DISCUSSIONS OF A PROPOSED Standard Review Plan (SRP) Section 17.3 on Quality Assurance

b. ENCLOSURE 3
A SUMMARY OF DISCUSSIONS OF A PROPOSED Resolution for GSI B-56, Diesel Generator Reliability

c. ENCLOSURE _____
A SUMMARY OF DISCUSSIONS OF A PROPOSED

2. MEMO FOR E. JORDAN FROM E. Miraglia DATED 6/4/90
FORWARDING REVIEW MATERIALS ON A PROPOSED Standard SRP Section 17.3 on Quality Assurance

3. MEMO FOR E JORDAN FROM E. Beckjord DATED 6/19/90
FORWARDING REVIEW MATERIALS ON A PROPOSED Resolution of GSI - B-56 "Diesel Reliability

4. MEMO FOR E JORDAN FROM _____ DATED _____
FORWARDING REVIEW MATERIALS ON A PROPOSED

(190)

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

June 4, 1990

MEMORANDUM FOR: Edward L. Jordan, Chairman
Committee to Review Generic Requirements

FROM: Frank J. Miraglia, Jr., Deputy Director
Office of Nuclear Reactor Regulation

SUBJECT: CRGR REVIEW OF STANDARD REVIEW PLAN CHAPTER 17, "QUALITY ASSURANCE," (SECTION 17.3)

NRR is proposing to revise Chapter 17, "Quality Assurance," of the Standard Review Plan. Enclosure 1 is the revised version as prepared by the Division of Licensee Performance and Quality Evaluation. It has been coordinated through the Inspection & Licensing Program Branch. It was also sent formally to the division director of each region's Division of Reactor Safety and to each of the other NRR technical division directors and informally to RES (Advanced Reactors and Generic Issues Branch) for review and comment. Enclosure 4 lists the comments received and our resolution. As indicated in Enclosure 4, the resolution of some of the comments has resulted in some changes in Enclosure 1. We are now asking for CRGR approval. Background leading to the revision and other pertinent information are given below.

In May 1984, the NRC completed a Congressionally mandated 15-month study of the causes of construction and design deficiencies in the commercial nuclear power industry. The report of that study was NUREG-1055, "Improving Quality and the Assurance of Quality in the Design and Construction of Nuclear Power Plants" (QA Report to Congress). The study's results, applicable not only to design and construction, but also to operations, modifications, decommissioning, and fuel reprocessing activities, confirmed that the regulatory foundation provided by 10 CFR 50, Appendix B was sound. However, the study concluded that the implementation of Appendix B was inadequate because the NRC overly emphasized form (program development and documentation) at the expense of substance (program implementation and effectiveness). The NUREG stated that, to meet the expectation of further improving quality, quality assurance should focus more on performance.

As a first step, the NRC staff introduced the concept of performance-based quality assurance in August 1987 in SECY 87-220, "Assurance of Quality." Since then, the staff has published NUREG/CR-5151, "Performance-Based Inspections," and implemented the "Inspecting for Performance" training course for NRC inspection personnel. The purpose of the "Inspecting for Performance" course and NUREG/CR-5151, which describes the course's methodology, is to broaden the scope and direction of NRC quality assurance activities by implementing inspection techniques that are based on observing and evaluating work-related activities affecting plant reliability and safety. A course modeled after the NRC's "Inspecting for

9006120122

Performance" course has been developed and is being taught within the nuclear industry.

To reinforce the performance-based inspection philosophy, the NRC headquarters staff developed TI 2515/78, "Inspection of Quality Verification Functions," (later, MC 35702) and conducted a series of inspections with the regions' staffs that increased the inspectors' emphasis on actual observation of ongoing work and reduced the emphasis on document and program reviews. By focusing attention on activities that are important to safe and reliable plant operations, the NRC's performance-based inspections were a model that encouraged licensees' verification and oversight organizations to conduct themselves similarly and to manage and operate their facilities in a more performance-based manner.

In 1988, the NRC's Light-Water Reactor Inspection Program for Plant Operations (Manual Chapter 2515) was revised to more clearly require inspection of licensee performance in technical disciplines, such as operations, maintenance, radiological controls, engineering, physical security, and environmental protection. That inspection program provides additional inspection guidance to follow up on operational events and safety issues and to investigate the root causes and corrective actions related to identified concerns. With those changes, the NRC's inspection program for operations now provides greater flexibility in applying inspection resources to deal with issues of plant reliability and safety.

Section 17.3 of the Standard Review Plan (Enclosure 1) puts into place a performance-oriented quality assurance program review plan for all phases of a nuclear power plant. Highlights of Section 17.3 are as follows:

1. It eliminates the current fragmentation and overlap of the self-assessment function responsibilities, including safety committee activities, audits, and other independent assessments.

2. It simplifies the format, clarifies the intent, and consolidates the text of the present SRP.

3. It permits the use of up-to-date industry consensus standards (with recognition of specific NRC guidance in current Regulatory Guides).

We are submitting Section 17.3 of the Standard Review Plan for CRGR approval. Because Section 17.3 does not represent any new staff positions and because it will apply only to applicants of new nuclear power and fuel reprocessing plants, a backfit in accordance with 10 CFR 50.109 does not exist. Note, too, that licensee-proposed revisions of quality assurance program descriptions that have been accepted by the staff will continue to be reviewed against their original acceptance criteria, Sections 17.1 or Section 17.2, not against Section 17.3. (This is why Sections 17.1 and 17.2 are

not being deleted.) We do intend, however, to permit current licensees to adopt Section 17.3 if they choose to do so.

The proposed revision to the SRP is a Type I revision, as defined in NRR Office Letter No. 800. The format of Section 17.3 is substantially different from that of Sections 17.1 and 17.2. However, it neither incorporates new or revised requirements nor substantively changes the existing guidance. Therefore, we do not believe it is necessary to issue it for public comment.

Enclosures 2 and 3 are provided to assist your review. Enclosure 2 lists each element of Sections 17.1 and 17.2 of the Standard Review Plan and indicates where the element is reflected in Section 17.3. Enclosure 2 also shows the disposition of those elements which no longer specifically appear. Enclosure 3 includes Sections 17.1 and 17.2 of the present Standard Review Plan.

Any questions you or your staff may have may be directed to Eileen McKenna (X-21010) or Jack Spraul (X-21023).

Frank J. Miraglia Jr

Frank J. Miraglia, Jr., Deputy Director
Office of Nuclear Reactor Regulation

Enclosures:
As Stated

cc w/enclosures:
CRGR (20)
ACRS (15)

Enclosure 1

SRP Section 17.3

(Proposed)

U.S. NUCLEAR REGULATORY COMMISSION

# STANDARD REVIEW PLAN

OFFICE OF NUCLEAR REACTOR REGULATION

## 17.3 QUALITY ASSURANCE PROGRAM DESCRIPTION

REVIEW RESPONSIBILITIES

Primary - Performance and Quality Evaluation Branch (LPEB)

Secondary - None

### I. AREAS OF REVIEW

LPEB reviews and evaluates new quality assurance program descriptions (QAPDs) as submitted by the applicant. LPEB or appropriate Regional personnel review and evaluate proposed QAPD changes. A QAPD may be a quality assurance topical report or part of a safety analysis report. The reviews address the quality assurance controls for the activities encompassed by the submittal that may affect the quality of items important to safety.

The QAPD is a top-level policy document in which a facility's management sets the tone and establishes the manner in which quality is to be achieved. It is a product of senior-level management, and it represents an organization's overall philosophy regarding quality.

The individual performing the work determines the level of quality that is achieved. Therefore, the applicant must develop and maintain a philosophy whereby each individual, properly trained and motivated, achieves the highest quality of performance of which he or she is capable. This emphasis on individual performance reinforces the importance of the self-assessment process, the object of which is to independently review and evaluate overall performance. It also underscores management's role to provide integration, discipline, and the required support to ensure success.

This section of the Standard Review Plan (SRP) is organized into the three discrete areas of activity: management, performance/verification, and self-assessment. Encompassed within the three areas are the 18 quality assurance (QA) criteria of 10 CFR Part 50, Appendix B. The SRP outlines a standardized QA program for construction permit holders, their principal contractors, and operating facility licensees. The QA program applies to all phases of a facility's life, including design, construction, operation, modification, and decommissioning.

A. MANAGEMENT

1. Methodology
2. Organization
3. Responsibility
4. Authority
5. Personnel Training and Qualification
6. Corrective Action
7. Regulatory Commitments

B. PERFORMANCE/VERIFICATION

1. Methodology
2. Design Control
3. Design Verification
4. Procurement Control
5. Procurement Verification
6. Identification and Control of Items
7. Handling, Storage, and Shipping
8. Test Control
9. Measuring and Test Equipment Control
10. Inspection, Test, and Operating Status
11. Special Process Control
12. Inspection
13. Corrective Action
14. Document Control
15. Records

C. SELF-ASSESSMENT

1. Methodology
2. Assessment

II. ACCEPTANCE CRITERIA

This section outlines and specifies the NRC's acceptance criteria for QAPDs. Criterion 1 of 10 CFR Part 50, Appendix A, "General Design Criteria for Nuclear Power Plants," requires that a QA program be established and implemented. Appendix B of 10 CFR Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," specifies 18 quality criteria which must be addressed in a QAPD. Except when acceptable alternatives are provided, the acceptance criteria that follow provide attributes to be addressed for

a QAPD to be found acceptable. The QAPD should describe how each of the acceptance criteria will be met.

A. MANAGEMENT

1. Methodology

a. At the most senior management level, the applicant (that is, the organization applying to have its QAPD reviewed and accepted by the NRC) is to issue a written QAPD that establishes the quality policy and commits the organization to implement it.

b. The QAPD is to be binding on all personnel, including management personnel having responsibility for costs and schedules.

c. The QAPD is to include the criteria used to identify the items and activities to which the QA program applies. A list of items under the control of the quality assurance program is to be established and maintained.

d. The QAPD is to provide measures to ensure the quality of items and activities to an extent consistent with their importance to safety.

2. Organization

a. The QAPD is to contain an organizational description that addresses the organizational structure, functional responsibilities, levels of authority, and interfaces. The organizational description is to include the onsite and offsite organizational elements that function under the cognizance of the QA program. Functional responsibilities include activities such as preparing, reviewing, approving, and verifying designs; qualifying suppliers; preparing, reviewing, approving, and issuing instructions, procedures, schedules, and procurement documents; purchasing; verifying supplier activities; identifying and controlling acceptable and nonconforming hardware and software; manufacturing; calibrating and controlling measuring and test equipment; qualifying and controlling special processes; constructing; inspecting; testing; startup; operating; performing maintenance; performing the self-assessment function; decommissioning; and controlling records.

b. There is to be independence between persons and organizations executing performance activities and those executing verification and self-assessment activities. The degree of independence may be commensurate with the activity's relative importance to safety.

c. The person filling the most senior-level management position is responsible for implementing the QA policy and program.

d. A management position, in which the responsibility for carrying out the self-assessment function, including independent review-group activities, audits, and other independent assessments resides, is to be established. The person filling this position is to:

(1) Have sufficient authority and organizational freedom to implement assigned responsibilities.

(2) Report at a management level sufficiently high to ensure that cost and schedule considerations do not unduly influence decision making.

(3) Have effective lines of communication with persons in other senior management positions.

(4) Have no unrelated duties or responsibilities that would preclude full attention to assigned responsibilities.

When site activities warrant, an onsite management position is to be established for which the above characteristics and responsibilities for the onsite activities apply.

e. Major delegation of work to participants outside the applicant's organization is to be identified and described as follows:

(1) The organizational elements responsible for delegated work are to be identified.

(2) Management controls and lines of communication between the applicant and the delegated organization are to be established.

(3) Responsibility for the QA program and the extent of management oversight by the applicant are to be established.

(4) The performance of delegated work is to be formally evaluated by the applicant.

3. Responsibility

a. The applicant is to retain and exercise the responsibility for the scope and implementation of an effective overall QA program.

b. The applicant may delegate part or all of the activities of planning, establishing, and implementing the overall QA program to others, but is to retain the responsibility for the program's effectiveness.

c. Senior-level management is to assess annually the adequacy of the QA program's implementation.

d. The applicant is responsible for ensuring that the applicable portion of the QA program is properly documented, approved, and implemented (people are trained and resources are available) before an activity within the scope of the QA program is undertaken by the applicant or by others.

e. Individual managers are to ensure that personnel working under their management cognizance are provided the necessary training and resources to accomplish their assigned tasks.

f. The manager responsible for their implementation is to approve the procedures that implement the QA program. These procedures are to reflect the QA policy, and work is to be accomplished in accordance with them.

4. Authority

a. When the applicant delegates responsibility for planning, establishing, or implementing any part of the overall QA program, sufficient authority to accomplish the assigned responsibilities also is to be delegated.

b. Responsibility and authority to stop unsatisfactory work and control further processing, delivery, installation, or use of nonconforming items (such as structures, systems, components, parts, materials, equipment, consumable materials, and software) is to be assigned by the applicant such that cost and schedule considerations do not override safety considerations.

5. Personnel Training and Qualification

a. Personnel assigned to implement elements of the QA program are to be capable of performing their assigned tasks.

b. Training programs to ensure that personnel achieve and maintain suitable proficiency are to be established and implemented.

c. Personnel training and qualification records are to be maintained.

6. Corrective Action

a. Plant management, at all levels, is to foster a "no-fault" attitude toward the identification of conditions that are adverse to quality, such as failures, malfunctions, nonconformances, and out-of-control processes including the failure to follow procedures.

b. A corrective action program is to be established and implemented that includes prompt identification, documentation, lassification, cause analysis, correction of the conditions, elimination of the cause of significant conditions, and followup of conditions that are adverse to quality. The program is to include provisions that ensure that corrective actions are not inadvertently nullified by subsequent actions.

c. Specific responsibilities within the corrective action program may be delegated, but the applicant is to maintain responsibility for the program's effectiveness.

d. Nonconforming items (those that do not meet quality requirements) are to be properly controlled to prevent their inadvertent test, installation, or use. They are to be reviewed and either accepted, rejected, repaired, or reworked.

e. Reports of conditions that are adverse to quality are to be analyzed to identify trends in quality performance. Significant conditions adverse to quality and significant trends are to be reported to the appropriate level of management.

7. Regulatory Commitments

a. The applicant is to comply with 10 CFR Part 21, Criterion 1 of Appendix A to 10 CFR Part 50, Appendix B to 10 CFR Part 50, 10 CFR 50.55a, and 10 CFR 50.55(e) as part of the overall QA program.

b. Except where acceptable alternatives are provided, the applicant is to comply with the regulatory positions in the appropriate revisions of the regulatory guides listed in Section VI.A of this chapter. Section VI.A lists regulatory guides issued in response to Appendix B to 10 CFR Part 50. (Regulatory Guides 1.26 and 1.29 are included to ensure that acceptable QA requirements are specified for items that they address.)

c. Except where acceptable alternatives are provided, the applicant is to comply with the QA guidance in the appropriate revisions of the applicable documents listed in Section VI.B of this chapter. Section VI.B lists documents that contain programmatic QA guidance for

specific items and activities that are important to safety.

d. For Class 1, 2, and 3 items covered by Section III of the ASME Boiler and Pressure Vessel Code, the code QA requirements are to be supplemented by the guidance of the regulatory guides in Section VI.A.

e. The NRC is to be notified of QAPD changes in accordance with 10 CFR 50.54(a)(3) and 50.55(f)(3).

B. PERFORMANCE/VERIFICATION

1. Methodology

a. Personnel performing work activities such as design, engineering, procurement, manufacturing, construction, installation, startup, maintenance, modification, operation, and decommissioning are responsible for achieving acceptable quality.

b. Personnel performing verification activities are responsible for verifying the achievement of acceptable quality.

c. Work is to be accomplished and verified using instructions, procedures, or other appropriate means that are of a detail commensurate with the activity's complexity and importance to safety.

d. Criteria that define acceptable quality are to be specified, and verification is to be against these criteria.

2. Design Control

a. A program is to be established and implemented for the design of items that are important to safety.

b. The program is to include provisions to control design inputs, processes, outputs, changes, interfaces, records, and organizational interfaces.

c. Design inputs (such as the design bases and the performance, regulatory, quality, and quality verification requirements) are to be correctly translated into design outputs (such as specifications, drawings, procedures, and instructions).

d. The final design output is to relate to the design input in sufficient detail to permit verification.

e. The design process is to ensure that items and activities that are important to safety are selected and

independently verified consistent with their importance to safety to ensure they are suitable for their intended application.

f. Changes to final designs (including field changes and modifications) and dispositions of nonconforming items to use as is or repair are to be subjected to design control measures commensurate with those applied to the original design and approved by the organization that performed the original design or a qualified designate.

g. Interface controls (internal and external between participating design organizations and across technical disciplines) for the purpose of developing, reviewing, approving, releasing, distributing, and revising design inputs and outputs are to be defined.

h. Design records, maintained to provide evidence that the design was properly accomplished, are to include not only the final design output and revisions to the final output, but also the important design steps (calculations, analyses, and computer programs, for example) and the sources of input that support the final output.

3. Design Verification

a. A program is to be established and implemented to verify the acceptability of design activities and documents. Design inputs, processes, outputs, and changes are to be verified.

b. Verification methods include, but are not limited to, design reviews, alternative calculations, and qualification testing.

c. When a test program is used to verify the acceptability of a specific design feature, the test program is to demonstrate acceptable performance under conditions that simulate the most adverse design conditions that are expected to be encountered.

d. Independent design verification is to be completed before design outputs are used by other organizations for design work and before they are used to support other activities such as procurement, manufacture, or construction. When this timing cannot be achieved, the unverified portion of the design is to be identified and controlled. In all cases, the design verification is to be completed before relying on the item to perform its function and before its installation becomes irreversible (requiring extensive demolition or rework).

e. In exceptional circumstances, the designer's immediate supervisor can perform the design verification, provided (a) the supervisor is the only technically qualified individual capable of performing the verification, (b) the need is individually documented and approved in advance by the supervisor's management, and (c) the frequency and effectiveness of the supervisor's use as a design verifier are independently verified to guard against abuse.

f. Design verification procedures are to be established and implemented to ensure that an appropriate verification method is used, the appropriate design parameters to be verified are chosen, the acceptance criteria are identified, the verification is satisfactorily accomplished, and the results are properly recorded.

4. Procurement Control

a. A program is to be established and implemented to ensure that purchased items and services are of acceptable quality.

b. The program is to include provisions for evaluating prospective suppliers and selecting only qualified suppliers.

c. The program is to include provisions for ensuring that qualified suppliers continue to provide acceptable products and services.

d. The program is to include provisions (such as source verification, receipt inspection, pre-installation and post-installation tests, and certificates of conformance) for accepting purchased items and services.

e. Applicable technical, regulatory, administrative, and reporting requirements (such as specifications, codes, standards, tests, inspections, special processes, and 10 CFR Part 21) are to be invoked for procurement of items and services.

f. The program is to include provisions for ensuring that documentary evidence that an item conforms to procurement requirements is on site before the item is placed in service or used.

g. The program is to include provisions for ensuring that procurement, inspection, and test requirements have been satisfied before an item is placed in service or used.

h. The procurement of components, including spare and replacement parts, is to be subject to quality and technical requirements suitable for their intended

service and to the purchaser's current QA program requirements.

i. Appropriate controls for the selection, determination of suitability for intended use (critical characteristics), evaluation, receipt, and quality evaluation of commercial-grade items are to be imposed to ensure that they will perform satisfactorily in service.

5. Procurement Verification

a. A program is to be established and implemented to verify the quality of purchased items and services at intervals and to a depth consistent with the item's or service's importance to safety, complexity, and quantity and the frequency of procurement .

b. The program is to be executed in all phases of procurement. As necessary, this may require verification of activities of suppliers below the first tier.

6. Identification and Control of Items

a. A program is to be established and implemented to identify and control items (including consumable materials and items with limited shelf life) to prevent the use of incorrect or defective items.

b. Identification of each item is to be maintained throughout fabrication, erection, installation, and use so that the item can be traced to its documentation. Traceability is to be maintained to an extent consistent with the item's importance to safety.

7. Handling, Storage, and Shipping

a. A program is to be established and implemented to control the handling, storage, shipping, cleaning, and preserving of items to prevent their damage, loss, and deterioration.

b. Special protective measures (such as containers, shock absorbers, accelerometers, inert gas atmospheres, specific moisture content levels, and temperature levels) are to be specified and provided when required to maintain acceptable quality.

c. Specific procedures are to be developed and used for cleaning, handling, storage, packaging, shipping, and preserving items when required to maintain acceptable quality.

d. Items are to be marked and labeled during packaging, shipping, handling, and storage to identify, maintain,

and preserve the items' integrity and indicate the need for special controls.

8. Test Control

   a. A test control program is to be established and implemented to demonstrate that items will perform satisfactorily in service.

   b. Criteria are to be defined that specify when testing is required.

   c. The test control program is to include, as appropriate, proof tests before installation, pre-operational tests, post-maintenance tests, post-modification tests, and operational tests.

   d. Test procedures are to be developed that include (a) instructions and prerequisites to perform the test, (b) use of proper test equipment, (c) acceptance criteria, and (d) mandatory inspection hold points as required.

   e. Test results are to be documented and reviewed by the management of the testing organization and the management having responsibility for the item being tested.

   f. When acceptance criteria are not met, corrected areas are to be retested.

9. Measuring and Test Equipment Control

   a. A program is to be established and implemented to control the calibration, maintenance, and use of measuring and test equipment.

   b. The types of equipment covered by the program (such as instruments, tools, gages, reference and transfer standards, and nondestructive examination equipment) are to be defined.

   c. Measuring and test equipment is to be calibrated at specified intervals (or immediately before and after use) on the basis of the item's required accuracy, intended use, frequency of use, and stability characteristics and other conditions affecting its performance.

   d. Measuring and test equipment is to be labeled, tagged, or otherwise controlled to indicate its calibration status and to ensure its traceability to calibration test data.

   e. Measuring and test equipment is to be calibrated against standards that have an accuracy of at least four times the required accuracy of the equipment being calibrated

or, when this is not possible, have an accuracy that ensures the equipment being calibrated will be within the required tolerance.

f. If nationally recognized standards exist, calibration standards are to be traceable to them. Except where calibration standards with the same accuracy as the instruments being calibrated are shown to be adequate for the requirements, calibration standards are to have a greater accuracy than the standards being calibrated.

g. Measuring and test equipment found out of calibration is to be tagged or segregated and not used until it is recalibrated. The acceptability of items measured, inspected, or tested with an out-of-calibration device is to be determined.

10. Inspection, Test, and Operating Status

a. As applicable, inspection, test, and operating status of items is to be verified before their release, fabrication, receipt, installation, test, and use to preclude inadvertent bypassing of inspections and tests and to prevent inadvertent operation.

b. The application and removal of status indicators and other labels are to be controlled.

11. Special Process Control

a. A program is to be established and implemented to ensure that special processes, such as welding, heat treating, and nondestructive examination are properly controlled.

b. The criteria that establish which processes are special are to be described.

c. Special processes are to be accomplished by qualified personnel using qualified procedures and equipment in accordance with applicable codes, standards, specifications, criteria, and other special requirements.

12. Inspection

a. A program is to be established and implemented for inspections (source, in-process, final, receipt, maintenance, modification, in-service, operations, and decommissioning). The inspection program may be implemented by or for the organization performing the activity to be inspected.

b. Provisions to ensure inspection planning is properly accomplished are to be established. Planning activities are to identify the characteristics and activities to be

inspected, the inspection techniques, the acceptance criteria, and the organization responsible for performing the inspection.

c. Provisions to identify inspection hold points, beyond which work is not to proceed without the consent of the inspection organization, are to be defined.

d. Inspection results are to be documented by the inspector and reviewed by management.

e. When acceptance criteria are not met, corrected areas are to be reinspected.

13. Corrective Action

a. Performance and verification personnel are to (a) identify conditions that are adverse to quality, (b) suggest, recommend, or provide solutions to the problems, and (c) verify resolution of the issue.

b. Reworked, repaired, and replacement items are to be inspected and tested in accordance with the original inspection and test requirements or specified alternatives.

14. Document Control

a. A program is to be established and implemented to control the development, review, approval, issue, use, and revision of documents.

b. The scope of the document control program is to be defined. Examples of documents to be controlled include design drawings, as-built drawings, engineering calculations, design specifications, computer codes, purchase orders and related documents, vendor-supplied documents, audit and surveillance procedures, operating procedures, emergency operating procedures, technical specifications, nonconformance reports, corrective action reports, work instructions and procedures, calibration procedures, quality verification procedures, and inspection and test reports.

c. Revisions of controlled documents are to be reviewed for adequacy and approved for release by the same organization that originally reviewed and approved the documents or by a designated organization that is qualified and knowledgeable.

d. Controlled copies of instructions and procedural documents are to be distributed to and used by the person performing the activity.

e. The distribution of new and revised controlled documents is to be in accordance with established timeliness guidelines. Superseded documents are to be controlled.

15. Records

a. A program is to be established and implemented to ensure that sufficient records of items and activities (such as design, engineering, procurement, manufacturing, construction, inspection and test [such as manufacturer's, proof, receipt, pre-operational, and post-installation], installation, pre-operation, startup, operations, maintenance, modification, decommissioning, and audits) are generated and maintained to reflect completed work.

b. The program is to provide provisions for the administration, receipt, storage, preservation, safekeeping, retrieval, and disposition of records.

C. SELF-ASSESSMENT

1. Methodology

a. Personnel responsible for carrying out the self-assessment function, including safety committee activities, audits, and other independent assessments, are to be cognizant of day-to-day activities so that they can act in a management advisory function. For example, during the operations phase of a nuclear power plant, this would involve monitoring the overall performance of the plant, identifying anomalous performance and precursors of potential problems, reporting findings in an understandable form and in a timely fashion to a level of line management having the authority to effect corrective action, reporting results back to line management, and verifying satisfactory resolution of problems.

b. Organizations performing self-assessment activities are to be technically and performance oriented, with their primary focus on the quality of the end product and a secondary focus on procedures and processes.

c. Personnel performing self-assessment activities are not to have direct responsibilities in the area they are assessing.

d. Self-assessments are to be accomplished using instructions, procedures, or other appropriate means that are of a detail commensurate with the activity's complexity and importance to safety.

2. Assessment

a. A program of planned and periodic assessments is to be established and implemented to confirm that activities affecting quality comply with the QA program and that the QA program has been implemented effectively.

b. Assessments are to provide comprehensive independent evaluation of activities and procedures.

c. Planning activities are to identify the characteristics and activities to be assessed and the acceptance criteria.

d. Scheduling and resource allocation are to be based on the status and safety importance of the activity or process being assessed.

e. Scheduling is to be dynamic and resources are to be supplemented when QA program effectiveness is in doubt.

f. Assessment results are to be documented and reviewed by the assessor's management and by management having responsibility in the area assessed. Follow-up action, including a re-look at deficient areas, is to be initiated as necessary.

g. When any work carried out under the requirements of the QA program is delegated to others, implementation of that part of the work is to be assessed by the applicant.

h. Assessments are to be conducted using predetermined acceptance criteria.

III. REVIEW PROCEDURES

New QAPDs will be reviewed against the acceptance criteria described in Section II, including the applicant's commitment to the applicable references listed in Section VI. Any exceptions or alternatives to this SRP section, including the applicable references in Section VI, will be reviewed to ensure that they are defined and that an adequate basis exists for their acceptance. When required, the Performance and Quality Evaluation Branch will prepare a request for additional information for the applicant and review the response for acceptability.

Changes to a QAPD previously accepted by the NRC will be reviewed to determine their acceptability. The changed QAPD will be compared against the previously accepted QAPD, its controls, and the appropriate controls in Chapter 17 of the Standard Review Plan to determine the acceptability of the changes. When required, the reviewing organization will prepare a request for additional information for the applicant and review the response for acceptability.

Upon concluding that the QAPD describes an acceptable quality assurance program, the reviewing organization may request that an inspection be performed by NRR or Regional personnel as appropriate. The inspection will assess the applicant's interpretation and translation of the QAPD commitments into its procedures, processes, and organizational staffing. The inspection will focus on the effectiveness of the QAPD implementation.

Through review of the information provided by the applicant and, as required, meetings with the applicant, review of applicable NRC inspection reports, and discussion with involved NRC inspectors, a judgment is made of the applicant's capability to carry out its quality assurance responsibilities. The reviewer's satisfaction with the quality assurance program commitments, the description of how the commitments will be met, the organizational arrangements, and the capabilities to fulfill the QAPD should lead to the conclusion of acceptability as described in Section IV.

IV. EVALUATION FINDINGS

The reviewer will verify that sufficient information has been provided and that the review is sufficiently complete to support conclusions of the following type in either the staff's safety evaluation report (SER) or a letter to the applicant:

On the basis of the staff's detailed review and evaluation of the quality assurance program description (QAPD) in the (topical report or safety analysis report) for (nuclear facility), we conclude the following:

1. The QAPD acceptably describes the authority and responsibility of management and supervisory personnel, performance/verification personnel, and self-assessment personnel.

2. The organizations and persons responsible for performing the verification and self-assessment functions have the authority and independence to conduct their activities without undue influence from those directly responsible for costs and schedules.

3. The QAPD describes a philosophy and controls that, when properly implemented, comply with the requirements of Appendix B and Criterion 1 of Appendix A to 10 CFR Part 50, 10 CFR Part 21, 10 CFR 50.55a, and 10 CFR 50.55(e), with the criteria contained in SRP Section 17.3, and with the regulatory positions in the following regulatory guides:

   | Regulatory Guide | Title | Revision or Date |
   |---|---|---|

4. The QA program applies to activities and items that are important to safety.

5. Accordingly, the staff concludes that the applicant's QAPD complies with the applicable NRC regulations and industry

standards and can be implemented for the (Specify the application).

A brief description of the applicant's QA program that highlights the more important aspects of the program is to be provided in the SER.

V. IMPLEMENTATION

Except in those cases where the applicant proposes an acceptable alternative method for complying with the specified portions of the Commission's regulations and guidance, the method described herein will be used by the staff to evaluate conformance with Commission regulations. Licensee-proposed revisions of quality assurance program descriptions that have been accepted by the staff in accordance with 17.1 or 17.2 will continue to be reviewed against their original acceptance criteria. However, current licensees may adopt Section 17.3 if they choose to do so.

VI. REFERENCES

A. Regulatory guides issued in response to Appendix B of 10 CFR Part 50:

1. Regulatory Guide 1.8, "Personnel Selection and Training."

2. Regulatory Guide 1.26, "Quality Group Classification, and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants."

3. Regulatory Guide 1.28, "Quality Assurance Program Requirements (Design and Construction)," using NQA-1 and NQA-2.

4. Regulatory Guide 1.29, "Seismic Design Classification."

5. Regulatory Guide 1.33, "Quality Assurance Program Requirements (Operations)," with appropriate substitution of NQA-1 and NQA-2 for N-45.2 and its daughter standards.

B. Other Programmatic QA Guidance:

1. Fire protection QA controls are to be in accordance with Regulatory Positions 2 and 4 of Branch Technical Position CMEB 9.5-1 as given in SRP Section 9.5.1.

2. Radioactive waste QA controls are to be in accordance with Regulatory Position 6 of Regulatory Guide 1.143, "Design Guidance for Radioactive Waste Management Systems, Structures, and Components Installed in Light Water-Cooled Nuclear Power Plants."

3. Software verification is to be in accordance with the regulatory position in Regulatory Guide 1.152, "Criteria for

Programmable Digital Computer System Software in Safety-Related Systems of Nuclear Power Plants."

4. Regulatory Guide 1.54, "Quality Assurance Requirements for Protective Coatings Applied to Water-Cooled Nuclear Power Plants."

5. Regulatory Guide 2.5, "Quality Assurance Program Requirements for Research Reactors."

6. Regulatory Guide 3.3, "Quality Assurance Program Requirements for Fuel Reprocessing Plants and for Plutonium Processing and Fuel Fabrication Plants."

7. Regulatory Guide 3.21, "Quality Assurance Requirements for Protective Coatings Applied to Fuel Reprocessing and to plutonium Processing and Fuel Fabrication Plants."

8. Regulatory Guide 4.15, "Quality Assurance for Radiological Monitoring Programs (Normal Operations) - Effluent Streams and the Environment."

9. Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material."

10. Generic Letter 89-02 and its endorsement of EPRI NP-5652, "Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety-Related Applications (NCIG-07)."

Enclosure 2

SRP Comparison

# SRP COMPARISON

| Rev. 2 SRP 17.1 & 17.2 Item | Rev. 0 SRP 17.3 Disposition (M = Management) (P = Performance/Verification) (SA = Self-Assessment) |
|---|---|
| **1. ORGANIZATION** | |
| 1A1 | M - Responsibility "a" |
| 1A2 | M - Organization "a" & "e" |
| 1A3a | M - Organization "e"(3) |
| b | M - Organization "e"(4) |
| c | M - Organization "e"(1) |
| 1A4 | M - Organization "e"(2) |
| 1A5 | M - Organization "a". Quality assurance (QA) is recognized to consist of management, performance, verification of performance, and self-assessment. The SRP is a performance-oriented plan that establishes goals and objectives for safety and reliability. Because the size of the staff required to achieve the goals is the prerogative of the applicant's management, the requirement to describe the criteria for determining the size of the QA organization including the inspection staff has been deleted. |
| 1A6 | M - Organization "a" |
| 1B1 | M - Organization "c" |
| a | M - Organization "d"(1) & (2) |
| b | M - Organization "d"(3) |
| c | M - Methodology "a"<br>P - Document Control "a" requires review of procedures that implement the QA program, and M - Responsibility "e" requires that these procedures be approved by the manager responsible for their implementation. Additional approval is not required. Personnel performing the self-assessment function will audit per SA - Assessment "a" to verify acceptable work output. Auditor independence is addressed in M - Organization "b" and training in M -Personnel Training & Qualification. |
| d | M - Organization "d"(4) |
| 1B2 | The responsibility to verify conformance to established requirements can now be met by the performing organization. Personnel performing the self-assessment function will audit per SA - Assessment "a" to verify acceptable work output. Auditor independence is addressed in M - Organization "b" and training in M -Personnel Training & Qualification. |
| 1B3 | M - Corrective Action "a"<br>P - Corrective Action "a" |

| | |
|---|---|
| 1B4 | M - Authority "b" requires that the responsibility and authority to stop unsatisfactory work be assigned. It does not require that designated QA personnel have this responsibility and authority. |
| 1B5 | Deleted requirement to describe how disputes involving quality are resolved. This is standard management prerogative. |
| 1B6 | SA - Methodology "a" |
| 1C1 | M - Methodology "a" & "b" |
| 1C2(1) | M - Organization "c" |
| (2) | M - Organization "d"(2) |
| (3) | M - Personnel Training & Qualification |
| (-) | M - Organization "d"<br>M - Personnel Training & Qualification "a" requires that personnel be capable of performing their assigned tasks. It does not specifically require that the qualifications of the QA manager are at least equivalent to those described in Section 4.4.5 of ANSI/ANS-3.1-1978. |
| RG 1.8 | M - Regulatory Commitments "b" (VI.A.3 & .5) |

**2. QUALITY ASSURANCE PROGRAM**

| | |
|---|---|
| 2A1a(1) | M - Methodology |
| (2) | M - Methodology "c" requires that the QAPD include criteria to identify the QA program scope. A list is required, but not in the QAPD. |
| b | P - Test Control "c" |
| c | M - Methodology "c" requires that the QAPD include criteria to identify the QA program scope. It does not specify that computer code programs must be included. Software controls are required by NQA-2.7 (draft). |
| d | M - Regulatory Commitments "c" (VI.b.1) |
| e | M - Responsibility "e" |
| 2A2 | M - Methodology "a" |
| 2b1a(1) | M - Responsibility "f"<br>P - Document Control "a" |
| a(2) | P - Document Control |
| a(3) | M - Responsibility "f" |
| b | Procedures can now be reviewed by the organization that prepared them. Personnel performing the self-assessment function will audit per SA - Assessment "a" to verify acceptable work output. Auditor independence is addressed in M - Organization "b" and training in M -Personnel Training & Qualification. |
| c | M - Methodology "a" |
| d | P - Procurement Control "b"<br>M - Responsibility "d" |
| 2b2 | M - Regulatory Commitments "e" |
| 2b3(1) | M - Regulatory Commitments "b" |

| | |
|---|---|
| (2) | M - Regulatory Commitments "a" |
| (3) | M - Regulatory Commitments "a" |
| (4) | M - Regulatory Commitments "d" |
| (5) | M - Regulatory Commitments "b" requires commitment to appropriate revisions of regulatory guides. The NRC reviewer is to verify the correct revision. |
| (6) | M - Regulatory Commitments "c" |
| (7) | M - Regulatory Commitments "b" requires commitment to appropriate revisions of regulatory guides. The NRC reviewer is to verify the correct revision. |
| (8) | M - Regulatory Commitments "b" requires commitment to appropriate revisions of regulatory guides. It does not specifically require that the QA and technical organizations participate early in the QA program to determine the extent QA controls are to be applied to specific items. SA - Assessment "a" requires a program to confirm that activities affecting quality comply with the QA program and that the program has been implemented effectively. |
| (9) | M - Methodology "d" |
| 2B4 | M - Responsibility "f" requires QA procedures. A specific list of these procedures is no longer required in the QAPD. |
| 2B5 | The last sentence of the first paragraph of part II states that the QAPD should describe how each of the acceptance criteria will be met, and a QAPD meeting SRP Chapter 17 will provide acceptable details of how the QA program will be implemented. There is no need for an acceptance criterion that requires the QAPD to emphasize "how." |
| 2C1a | SA - Assessment "a" incorporates the audit program in the self-assessment program, the function of which is to keep upper management informed of the effectiveness of the overall QA program implementation. |
| b(1) | M - Responsibility "c" |
| b(2) | M - Corrective Action |
| 2C2 | M - Responsibility "d" |
| 2C3 | M - Organization "a" requires an organizational description that includes interfaces. The specific summary description of transfer of responsibilities from principal contractors to the licensee is not required. |
| 2Da | Specific requirements (goals and objectives) for training and qualification are given in M - Personnel Training & Qualification. |
| b | Same as 2Da |
| c | Same as 2Da |
| d | Same as 2Da |
| e | Same as 2Da |
| f | Same as 2Da |
| g | M - Regulatory Commitments "b" (VI.A.3 & .5) |

**3. DESIGN CONTROL**

| | |
|---|---|
| 3A(1) | P - Design Control "a" & "c"<br>P - Design Verification "a" |
| (2) | P - Design Control addresses engineering activities. The shopping list of engineering activities has been deleted. All activities important to safety are to be covered as required by M - Methodology "d". |
| 3B | M - Organization "a"<br>P - Design Control "h" addresses design records. The shopping list of design documents has been deleted. |
| 3C1 | M & P - Corrective Action address errors and deficiencies. They do not specifically address errors and deficiencies in approved design documents and computer codes. |
| 3C2 | M & P - Corrective Action address deviations. They do not specifically address deviations from engineering standards. |
| 3D | P - Design Control "g" |
| 3E1 | P - Design Verification "a" requires a program for independent verification of designs. It does not specifically require a check to verify dimensional accuracy and completeness of drawings and specifications. |
| 3E2 | The responsibility to review design drawings and specifications can now be met by the performing organization. Personnel performing the self-assessment function will audit per SA - Assessment "a" to verify acceptable work output. Auditor independence is addressed in M - Organization "b" and training in M -Personnel Training & Qualification. |
| 3E3 | P - Design Verification "a" & "b" |
| 3E4a | P - Design Verification "a" & "d"<br>M - Personnel Training & Qualification |
| (1) | P - Design Verification "e" |
| (2) | Same as 3E4a(1) |
| (3) | Same as 3E4a(1) |
| b | P - Design Verification "d" |
| c | P - Design Verification "f". Deleted shopping list of design documents. |
| d | P - Design Verification "f" |
| 3E3 a | P - Design Verification "f" |
| (#2)b | P - Design Verification "d" |
| c | P - Design Verification "c" |
| 3E4 (#2) | M - Methodology "d" requires measures to ensure quality. It does not specifically require that verified computer codes are certified for use and that their use is specified. SA - Assessment "a" requires a program to confirm that activities affecting quality |

comply with the QA program and that the QA program has been implemented effectively.

3F1 P - Design Control "f"

3F2 M - Regulatory Commitments "b" (VI.A.3 & .5)

**4. PROCUREMENT DOCUMENT CONTROL**

4A1 P - Document Control "a" & "b"
M - Responsibility "d"
M - Personnel Training & Qualification

4A2 P - Document Control "a" & "b" require review and approval of procurement documents. The shopping list of what must be reviewed has been deleted.

4B1 Activities addressed as follows:
.1 P - Procurement Control "a"
.2 P - Document Control
.3 P - Procurement Control "b"
.4 P - Procurement Control "b"
.5 M - Responsibility "d"
.- M - Organization "a"

4B2 M - Regulatory Commitments "b" (VI.A.3 & .5)

**5. INSTRUCTIONS, PROCEDURES, AND DRAWINGS**

5A P - Methodology "b"

5b P - Methodology "b" & "d"
P - Inspection "b"
P - Design Verification "f"
P - Test Control "d"(c)
SA - Assessment "c"

**6. DOCUMENT CONTROL**

6A1 P - Document Control "b"

6A2 The responsibility to review the technical adequacy and quality requirements of documents can now be met by the performing organization. Personnel performing the self-assessment function will audit per SA - Assessment "a" to verify acceptable work output. Auditor independence is addressed in M - Organization "b" and training in M - Personnel Training & Qualification.

6A3 P - Document Control "c"
P - Design Control "f"

6A4 P - Document Control "d"

6B1 P - Document Control "e"

6B2 P - Document Control "a" requires a program to control the development, review, approval, issue, use, and revision of documents, and P - Document Control "e" addresses timeliness of document distribution and requires control of superseded documents. The SRP

does not specifically require a master list or equivalent system to identify current revisions of documents. SA - Assessment "a" requires a program to confirm that activities affecting quality comply with the QA program and that the QA program has been implemented effectively.

6C1 P - Document Control "b" & "e"

## 7. CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

7A1 M - Organization "a"

7A2 M - Organization "a"
P - Procurement Verification "a" requires a program to verify supplier quality. It does not specifically require participation by the QA organization. SA - Assessment "a" requires a program to confirm that activities affecting quality comply with the QA program and that the QA program has been implemented effectively.

7A3 P - Procurement Control "b"
P - Document Control "b"
P - Records Control "a" requires the generation and maintenance of records sufficient to reflect completed work. Section 17.3 does not specifically require that supplier selection be documented and filed. Also, Section 17.3 does not refer to the CASE Register and LCVIP letters of confirmation since the vendor inspection program no longer issues LCVIP letters and the nuclear side of CASE has merged with NSQUAC to form NUPIC

7A4 P - Procurement Control "h" changes the requirement that spare and replacement parts be at least as good as the parts they replace to a requirement that they be suitable for their intended service.

7B1a P - Procurement Control "d"
b P - Procurement Control "d" & "g"
c P - Procurement Control "f" & "g"

7B2 P - Inspection, Test, & Operating Status "a" & "b"

7B3 P - Procurement Control "e" requires that reporting requirements be invoked on procurements, and P - Procurement Control "g" requires that procurement, inspection, and test requirements be met before an item is placed in service or used. The SRP does not require that suppliers give the following specific documents to the purchaser and that the purchaser review and accept these documents:

a. Documentation that identifies the purchased item and the specific procurement requirements (e.g., codes, standards, and specifications) met by the item

b. Documentation identifying any procurement requirements that have not been met
c. A description of nonconformances from the procurement requirements dispositioned "accept as is" or "repair"

7B4 P - Procurement Control "i"

7B5 P - Procurement Control "c" requires that provisions for ensuring that qualified suppliers continue to provide acceptable products and services be established and implemented. It does not specify how that is to be accomplished.

7B6 M - Regulatory Commitments "b" (VI.A.3 & .5)

**8. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS**

8A P - Identification & Control of Items "a"
M - Organization "a"

8B1 P - Identification & Control of Items "b"

8B2 P - Identification & Control of Items "b". Deleted shopping list of "appropriate" documentation.

8B3 Inspection, Test, & Operating Status "b" requires that the identification of each item be maintained throughout fabrication, erection, installation, and use. It does not specifically require that identification be verified before an item is released for fabrication, assembly, shipment, and installation. SA - Assessment "a" requires a program to confirm that activities affecting quality comply with the QA program and that the QA program has been implemented effectively.

**9. CONTROL OF SPECIAL PROCESSES**

9A1 P - Special Process Control "b" requires that the criteria for determining which processes are special be described. It does not require a list of special processes.

9A2 P - Special Process Control "c" requires that special processes be accomplished by qualified personnel using qualified procedures and equipment in accordance with the requirements, and M - Organization "a" requires a description of organizational responsibilities for qualifying and controlling special processes. The SRP does not require that the QA organization be involved. SA - Assessment "a" requires a program to confirm that activities affecting quality comply with the QA program and that the QA program has been implemented effectively.

9B1 P - Special Process Control "c" requires that special processes be qualified. It does not require that the

QA organization be involved. SA - Assessment "a" requires a program to confirm that activities affecting quality comply with the QA program and that the QA program has been implemented effectively.

9B2 P - Special Process Control "c"
P - Records "a" requires that records reflect completed work. It does not specifically require recording evidence of acceptable accomplishment of special processes.

9B3 P - Special Process Control "c"
P - Records "a" requires that records reflect completed work. It does not specifically require that qualification records be maintained of special processes.

**10. INSPECTION**

10A(1) P - Inspection "a" through "e"

(2) P - Inspection "a" and "b"

(3) M - Organization "a" requires a description of organizational responsibilities for inspections. It does not specifically require that the QA organization participate in these activities. SA - Assessment "a" requires a program to confirm that activities affecting quality comply with the QA program and that the QA program has been implemented effectively.

10B1(1) M - Organization "a"

(2) M - Organization "b" requires independence between performers and verifiers. It does not have the specific requirement that inspectors not report directly to the immediate supervisor responsible for the work being inspected. SA - Assessment "a" requires a program to confirm that activities affecting quality comply with the QA program and that the QA program has been implemented effectively.

(3) M - Organization "a" requires a description of organizational responsibilities for procedure review, M - Personnel Training & Qualification requires that tasks be accomplished by qualified personnel, and M - Organization "b" requires verifier independence. The SRP does not require QA organization involvement in these areas. SA - Assessment "a" requires a program to confirm that activities affecting quality comply with the QA program and that the QA program has been implemented effectively.

10B2 M - Personnel Training & Qualification

10C1a P - Inspection "b"

b P - Inspection "b"

c M - Organization "a"

d P - Inspection "b"

| | |
|---|---|
| e | P - Inspection "b" requires inspection planning. It does not specifically require that inspection procedures identify required drawings and specifications with applicable revisions. |
| f | P - Inspection "d" |
| g | P - Measuring & Test Equipment "a" and "c" |
| 10C2 | P - Inspection "c" |
| 10C3 | P - Inspection "d" |

**11. TEST CONTROL**

| | |
|---|---|
| 11A1(1) | P - Test Control "a" and "c" |
| (2) | P - Measuring & Test Equipment "a" and "c" |
| (3) | P - Test Control "a" and "b" |
| 11B1a | P - Test Control "d"(c)<br>P - Design Verification "f" |
| b | P - Test Control "d"(a) |
| c | P - Test Control "d"(a) requires that test prerequisites be in test procedures. The shopping list of test prerequisites has been deleted. |
| d | P - Test Control "d"(d) |
| e | P - Test Control "d"(c) |
| f | P - Test Control "e" |
| g | P - Test Control "d"(a) |
| 11C1 | P - Test Control "e" |

**12. CONTROL OF MEASURING AND TEST EQUIPMENT**

| | |
|---|---|
| 12.1 | P - Measuring & Test Equipment "a" |
| 12.2 | M - Organization "a" requires a description of organizational responsibilities for calibrating and controlling measuring and test equipment (M&TE). It does not require that the QA organization be involved.<br>SA - Assessment "a" requires a program to confirm that activities affecting quality comply with the QA program and that the QA program has been implemented effectively. |
| 12.3(1) | P - Measuring & Test Equipment "a"<br>P - Document Control "b" |
| (2) | P - Document Control "b" |
| (3) | P - Organization "a" |
| 12.4 | P - Measuring & Test Equipment "d" |
| 12.5 | P - Measuring & Test Equipment "a" requires a program to control M&TE. It does not require a description of the method of otherwise controlling M&TE when it is not labeled or tagged. |
| 12.6(1) | P - Measuring & Test Equipment "c" |
| (2) | P - Measuring & Test Equipment "e" |
| (3) | P - Records "a" requires records of completed work. It does not specifically require that the basis of |

acceptance of a lower accuracy ratio for calibrations be documented.

(4) M - Organization "a" requires a description of organizational responsibilities for calibration and control of M&TE. It does not specifically require the identity of management authorized to allow a lower calibration accuracy.

12.7(1) P - Measuring & Test Equipment "f"

(2) P - Measuring & Test Equipment "f"

(3) P - Records "a" requires records of completed work. It does not specifically require that the basis of acceptance of an equal accuracy ratio be documented.

(4) M - Organization "a" requires a description of organizational responsibilities for calibration and control of M&TE. It does not specifically require the identity of management authorized to allow an equal calibration accuracy.

12.8 P - Measuring & Test Equipment "f"
P - Records "a" requires records of completed work. It does not specifically require that the basis for calibration be documented if nationally recognized standards do not exist.

12.9 P - Measuring & Test Equipment "g"
P - Corrective Action "a"

**13. HANDLING, STORAGE, AND SHIPPING**

13.1(1) P - Handling, Storage, and Shipping "c"

(2) M - Personnel Training & Qualification

13.2 P - Methodology "b" requires that work be accomplished in accordance with instructions, procedures, or other appropriate means that are of a detail commensurate with the activity's complexity and safety importance. It does not specifically require procedures to control handling, storage, etc.

13.3 M - Regulatory Commitments "b" (VI.A.3 & .5)

**14. INSPECTION, TEST, AND OPERATING STATUS**

14.1 P - Methodology "b" requires that work be accomplished in accordance with instructions, procedures, or other appropriate means that are of a detail commensurate with the activity's complexity and safety importance, and P - Inspection, Test, & Operating Status "b" requires that the application and removal of status indicators and other labels be controlled. The SRP does not require procedures to specifically indicate the status of items.

14.2 P - Inspection, Test, & Operating Status "b"

14.3 P - Document Control "b" & "c"

14.4(1) P - Inspection, Test, & Operating Status "b"

M - Corrective Action "d"
(2) M - Organization "a"

**15. NONCONFORMING MATERIALS, PARTS, OR COMPONENTS**

15.1(1) M - Corrective Action "b"
(2) P - Methodology "b" requires that work be accomplished in accordance with instructions, procedures, or other appropriate means that are of a detail commensurate with the activity's complexity and safety importance, and P - Corrective Action "d" requires that nonconforming items be controlled. The SRP does not specifically require procedures to control nonconforming items.
(3) M - Organization "a"
15.2(1) M - Corrective Action "a" & "c"
M - Organization "a" requires a description of organizational responsibilities for controlling nonconforming items. It does not require that the QA organization be involved. SA - Assessment "a" requires a program to confirm that activities affecting quality comply with the QA program and that the QA program has been implemented effectively.
(2) M - Organization "a"
15.3(1) P - Document Control. Deleted shopping list of specific items that nonconformance documents include.
(2) P - Test Control "d"
M - Corrective Action "d"
15.4 M - Corrective Action "b"
P - Inspection "e"
15.5 M - Corrective Action "e" and "f"
M - Organization "a"

**16. CORRECTIVE ACTION**

16.1(1) M - Corrective Action "b"
(2) P - Methodology "b" requires that work be accomplished in accordance with instructions, procedures, or other appropriate means that are of a detail commensurate with the activity's complexity and safety importance. It does not specifically require procedures for the corrective action program.
(3) Corrective action procedures can now be reviewed by the organization that prepared them. Personnel performing the self-assessment function will audit per SA - Assessment "a" to verify acceptable work output. Auditor independence is addressed in M - Organization "b" and training in M - Personnel Training & Qualification.
16.2(1) M - Corrective Action "b"
P - Document Control

(2) M - Corrective Action "b" and P - Corrective Action "a" require verification of the resolution of conditions adverse to quality. They do not specifically require that the QA organization be involved. SA - Assessment "a" requires a program to confirm that activities affecting quality comply with the QA program and that the QA program has been implemented effectively.

16.3 M - Corrective Action "b" and P - Corrective Action "a" require verification of the resolution of conditions adverse to quality. They do not specifically require that corrective action be closed out in a timely manner or that the QA organization be involved. SA -Assessment "a" requires a program to confirm that activities affecting quality comply with the QA program and that the QA program has been implemented effectively.

16.4 M - Corrective Action "b" & "e"

**17. QUALITY ASSURANCE RECORDS**

17.1 P - Records "a"

17.2 M - Organization "a" requires a description of organizational responsibilities for records. It does not require that the QA organization be involved. SA - Assessment "a" requires a program to confirm that activities affecting quality comply with the QA program and that the QA program has been implemented effectively.

17.3 P - Records "a". Deleted the shopping list of items to be included in inspection and test records.

17.4 Deleted detailed requirements for record storage facility. Covered in M - Regulatory Commitments "b" (VI.A.3 & .5)

17.5 M - Regulatory Commitments "b" (VI.A.3 & .5)

**18. AUDITS**

18A1 SA - Assessment "a". Audits are now performed as part the self-assessment function.

a SA - Assessment "b" requires a comprehensive, independent evaluation of procedures and activities, and P - Methodology "c" requires independent verifications. The SRP does not specifically require that the QA organization perform these functions. SA - Assessment "a" requires a program to confirm that activities affecting quality comply with the QA program and that the QA program has been implemented effectively.

b Rather than requiring supplier audits, P - Procurement Control "c" specifies that provisions be established

to ensure that qualified suppliers continue to provide acceptable products and services.

18A2 SA - Assessment "a", "c", "d", and "e"

18A3 SA - Methodology "b" requires technically and performance-oriented self-assessments with a secondary focus on procedures and processes.

18A4 SA - Assessment "a". Deleted reference to Appendix B and the shopping list of areas to be audited.

18.B1 M - Corrective Action "e" requires that significant conditions adverse to quality and significant trends be reported to management. The specific requirement that the QA organization do this has been deleted. SA - Assessment "a" requires a program to confirm that activities affecting quality comply with the QA program and that the QA program has been implemented effectively.

18B2(1) SA - Methodology "d"

(2) M - Personnel Training & Qualification

(3) M - Organization "b"

18B3 M - Regulatory Commitments "b" (VI.A.3 & .5)

**Operations Phase**

1.1b M - Organization "a"

e M - Organization "d"

2.2 The SRP requires a QAPD for the complete life cycle. Therefore, the requirement that a QA program for operations be implemented at least 90 days before fuel loading is no longer specified.

2.3 The SRP requires a QAPD for the complete life cycle. The specific requirement for a commitment that the QA program described in the preliminary safety analysis report be implemented through preoperational testing has been deleted.

3.2 M - Personnel Training & Qualification
P - Document Control

6.2 The responsibility to review maintenance, modification, and inspection procedures can now be met by the performing organization. Personnel performing the self-assessment function will audit per SA - Assessment "a" to verify acceptable work output. Auditor independence is addressed in M - Organization "b" and training in M - Personnel Training & Qualification.

10.2 M - Personnel Training & Qualification
M - Organization "b" requires verifier independence. The SRP does not require that specific controls be met when inspections (verifications) associated with normal plant operations are performed by personnel within the same group as those who performed or supervised the work. Personnel performing the self-

assessment function will audit per SA - Assessment "a" to verify acceptable work output.

13.2 P - Handling, Storage, & Shipping requires an effective program for controlling items in storage. It does not specifically require that provisions be described for the storage of chemicals, reagents, lubricants, and other consumable materials (including control of shelf life).

17.2 P - Records "a" requires records of completed work. It does not specifically require that these records include operating logs, maintenance and modification procedures, related inspection results, reportable occurrences, and other records required by the technical specifications.

18.2 M - Organization "a"

Enclosure 3

SRP Sections 17.1 &17.2

(Current)

U.S. NUCLEAR REGULATORY COMMISSION

# STANDARD REVIEW PLAN

OFFICE OF NUCLEAR REACTOR REGULATION

## 17.1 QUALITY ASSURANCE DURING THE DESIGN AND CONSTRUCTION PHASES

REVIEW RESPONSIBILITIES

Primary - Quality Assurance Branch (QAB)

Secondary - Mechanical Engineering Branch
Instrumentation & Control Systems Branch
Power Systems Branch
Accident Evaluation Branch
Radiological Assessment Branch
Hydrologic & Geotechnical Engineering Branch
Containment Systems Branch

### I. AREAS OF REVIEW

QAB reviews and evaluates the description of the quality assurance (QA) program for the design and construction phases in each application for a construction permit (CP), a manufacturing license, or a standardized design approval in accordance with applicable portions of this section of the Standard Review Plan. The secondary review branches review the listing of structures, systems, and components (QA list) covered by the QA program for their areas of review responsibility in accordance with 2A1 of this section of the Standard Review Plan and documents the acceptability of the listing including any items that should be added or clarified by memo to the QAB. The review by MEB in this regard also addresses the areas of review responsibility normally assigned to ASB, RSB, CEB, PSB (except electrical), and SEB.

Pre-Docketing

Prior to docketing a CP application, the NRC performs a substantive review of the applicant's QA program description relative to ongoing design and procurement activities. This review and associated inspection are performed immediately after tendering of a CP application to determine that a satisfactory QA program has been established and is being implemented.

The pre-docketing substantive review places particular emphasis on the areas of organization, QA program, design control, procurement document control, and

audit. The application is not docketed unless the established and implemented program in these areas has no substantive deviation from NRC QA guidance applicable to activities conducted prior to docketing. Representatives from the offices of NRR and IE may meet with the applicant's representatives nine to twelve months prior to tendering of the application to provide a clear understanding of what is expected in the QA program description and the implemented program in order for the program to be accepted during the substantive review and associated inspection.

Where an NRC-accepted QA topical report is referenced in the application, the referenced QA program is not re-reviewed except for conformance to the applicable staff positions in this SRP section and the Regulatory Guides in effect at the time of docketing the application. For the case of CP applications referencing a standard design that includes an approved QA program directly or by reference, the applicant need not conform to new or revised Regulatory Guides unless they contain regulatory positions determined to be significant to safety, as indicated in the implementation section of each guide.

Post-Docketing

The QAB review, after docketing, covers the QA controls to be applied by the applicant and principal contractors to activities that may affect the quality of structures, systems, and components important to safety. These activities include site testing and evaluation (starting with evaluation of exposed excavated surfaces, determination of site characteristics, and testing), designing, purchasing, fabricating, constructing, handling, shipping, storing, cleaning, erecting, installing, inspecting, and testing. This review extends to the determination of how the applicable requirements of the eighteen criteria of Appendix B to 10 CFR 50 are satisfied by the proposed QA program.

The areas of review are as follows:

1. ORGANIZATION

   A. Organizational description and charts of the lines, interrelationships and areas of responsibility and authority for all organizations performing quality-related activities, including the applicant's organization and principal contractors (architect engineer, nuclear steam supply system vendor, constructor, and construction manager when other than the constructor).

   B. Organizational location, degree of independence from the performing organization, and authority of the individuals assigned the responsibility for performing QA functions.

   C. Organizational provisions for assuring the proper implementation of the QA program.

2. QUALITY ASSURANCE PROGRAM

   A. Scope of the QA program.

   B. Provisions to assure proper definition of the QA program.

   C. Programmatic provisions to assure proper implementation of the QA program.

D. Provisions to assure adequacy of personnel qualifications.

3. DESIGN CONTROL

A. Scope of the QA program for design activities.

B. The organizational structure, activity, and responsibility of the positions or groups responsible for design activities.

C. Provisions to carry out design activities in a planned, controlled, and orderly manner.

D. Provisions for interface control.

E. Provisions to verify or check the technical adequacy of design documents.

F. Provisions to control design changes.

4. PROCUREMENT DOCUMENT CONTROL

A. Provisions which assure that applicable regulatory requirements, technical requirements, and QA program requirements are included or referenced in procurement documents.

B. Provisions for review and approval of procurement documents.

5. INSTRUCTIONS, PROCEDURES, AND DRAWINGS

A. Provisions for assuring that activities affecting quality are prescribed by and accomplished in accordance with documented instructions, procedures, or drawings.

B. Provisions for including quantitative and qualitative acceptance criteria in instructions, procedures, and drawings.

6. DOCUMENT CONTROL

A. Provisions to assure that documents, including changes, are reviewed for adequacy, approved for release by authorized personnel, and distributed and used at the location where the prescribed activity is performed.

B. Provisions to prevent the inadvertent use of obsolete or superseded documents.

7. CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

A. Provisions for the control of purchased material, equipment, and services; for selection of suppliers; and for assessing the adequacy of quality.

B. Provisions to assure that documented evidence of the conformance of material and equipment to procurement requirements is available at the plant site prior to installation or use.

8. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

   A. Provisions to identify and control materials, parts, and components.

   B. Provisions to assure that incorrect or defective items are not used.

9. CONTROL OF SPECIAL PROCESSES

   A. Provisions to assure the acceptability of special processes such as welding, heat treating, nondestructive testing, and chemical cleaning.

   B. Provisions to assure that special processes are performed by qualified personnel using qualified procedures and equipment.

10. INSPECTION

   A. Provisions for the inspection of activities affecting quality, including the items and activities to be covered.

   B. Organizational responsibilities and qualifications established for individuals or groups performing inspections.

   C. Prerequisites to be provided in the written inspection procedures with provisions for documenting and evaluating inspection results.

11. TEST CONTROL

   A. Provisions for tests which assure that structures, systems, and components will perform satisfactorily in service.

   B. Prerequisites to be provided in written test procedures with provisions for documenting and evaluating test results.

   C. Personnel qualification programs established for test personnel.

12. CONTROL OF MEASURING AND TEST EQUIPMENT

   Provisions to assure that tools, gages, instruments, and other measuring and testing devices are properly identified, controlled, calibrated, and adjusted at specified intervals.

13. HANDLING, STORAGE, AND SHIPPING

   Provisions to control handling, storage, shipping, cleaning, and preservation of items in accordance with work and inspection instructions to prevent damage, loss, and deterioration by environmental conditions such as temperature or humidity.

14. INSPECTION, TEST, AND OPERATING STATUS

   Provisions to indicate the inspection, test, and operating status of items to prevent inadvertent use or bypassing of inspection and tests.

15. NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

Provisions to control the use or disposition of nonconforming materials, parts, or components.

16. CORRECTIVE ACTION

Provisions to assure that conditions adverse to quality are promptly identified and corrected and that measures are taken to preclude repetition.

17. QUALITY ASSURANCE RECORDS

Provisions for the identification, retention, retrieval, and maintenance of records that furnish evidence of activities affecting quality.

18. AUDITS

A. Provisions for audits to verify compliance with all aspects of the QA program and to determine the effectiveness of the QA program.

B. Responsibilities and procedures for auditing, documenting and reviewing audit results, and designating management levels to review and assess audit results.

## II. ACCEPTANCE CRITERIA

The applicant (and its principal contractors such as the NSSS vendor, A/E, constructor and construction manager) must establish a QA program for the design and construction phases in accordance with Appendix B to 10 CFR Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." The applicant's QA program (including its principal contractors) must describe in the PSAR or SSAR how each criterion of Appendix B will be met. The acceptance criteria used by the QAB to evaluate this QA program are listed in the following eighteen subsections. The acceptance criteria include a commitment to comply with the regulations, regulatory positions presented in the appropriate issue of the Regulatory Guides, and the Branch Technical Position listed in subsection V. Thus, the commitment constitutes an integral part of the QA program description and requirements. Exceptions and alternatives to these acceptance criteria may be adopted by applicants provided adequate justification is given; the QAB review allows for considerable flexibility in defining methods and controls while still satisfying pertinent regulations. When the QA program description meets the applicable acceptance criteria of this subsection or provides acceptable exceptions or alternatives, the program is considered to be in compliance with pertinent NRC regulations.

The review will ascertain that the commitments and the description of how the commitments are implemented, to the extent necessary, are objective and stated in inspectable terms.

The Organization (17.1.1) elements responsible for the QA program are acceptable if:

1A1.* The responsibility for the overall program is retained and exercised by the applicant.

1A2. The applicant has identified and described major delegation of work involved in establishing and implementing the QA program or any part thereof to other organizations.

1A3. When major portions of the applicant's program are delegated:

a. Applicant describes how responsibility is exercised for the overall program. The extent of management oversight should be addressed including the location, qualifications, and criteria for determining the number of personnel performing these functions.

b. Applicant evaluates the performance (frequency and method stated - once per year although longer cycle acceptable with other evaluations of individual elements) of work by the delegated organization.

c. Qualified individual(s) or organizational element(s) are identified within the applicant's organization as responsible for the quality of the delegated work prior to initiation of activities.

1A4. Clear management controls and effective lines of communication exist for QA activities among the applicant and the principal contractors to assure direction of the QA program.

1A5. Organization charts clearly identify all the "onsite" and "offsite" organizational elements which function under the cognizance of the QA program (such as design, engineering, procurement, manufacturing, construction, inspection, test, instrumentation and control, nuclear engineering, etc.), the lines of responsibility, and a description of the criteria for determining the size of the QA organization including the inspection staff.

1A6. The applicant (and principal contractors) describes the QA responsibilities of each of the organizational elements noted on the organization charts.

1B1. The applicant (and principal contractors) identifies a management position that retains overall authority and responsibility for the QA program (normally, this position is the QA Manager) and this position has the following characteristics:

a. Is at the same or higher organization level as the highest line manager directly responsible for performing activities affecting quality (such as engineering, procurement, construction, and operation) and is sufficiently independent from cost and schedule.

---

* The alphanumeric designation for each acceptance criterion in subsection II indicates its relationship to the areas of review identified in subsection I.

b. Has effective communication channels with other senior management positions.

c. Has responsibility for approval of QA Manual(s).

d. Has no other duties or responsibilities unrelated to QA that would prevent his full attention to QA matters.

1B2. Verification of conformance to established requirements (except for designs, ref. 3E2) is accomplished by individuals or groups within the QA organization who do not have direct responsibility for performing the work being verified or by individuals or groups trained and qualified in QA concepts and practices and independent of the organization responsible for performing the task.

1B3. Persons and organizations performing QA functions have direct access to management levels which will assure the ability to:

a. Identify quality problems.

b. Initiate, recommend, or provide solutions through designated channels.

c. Verify implementation of solutions.

Those persons and organizations with the above authority are identified and a description of how those actions are carried out is provided.

1B4. a. Designated QA personnel, sufficiently free from direct pressures for cost/schedule, have the responsibility delineated in writing to stop unsatisfactory work and control further processing, delivery, or installation of nonconforming material.

b. The organizational positions with stop work authority are identified.

1B5. Provisions are established for the resolution of disputes involving quality, arising from a difference of opinion between QA personnel and other department (engineering, procurement, manufacturing, etc.) personnel.

1B6. Designated QA individuals are involved in day-to-day plant activities important to safety (i.e., the QA organization routinely attends and participates in daily plant work schedule and status meetings to assure they are kept abreast of day-to-day work assignments throughout the plant and that there is adequate QA coverage relative to procedural and inspection controls, acceptance criteria, and QA staffing and qualification of personnel to carry out QA assignments).

1C1. Policies regarding the implementation of the QA program are documented and made mandatory. These policies are established at the Corporate President or Vice President level.

1C2. Position description (see 1B1) assures that the individual directly responsible for the definition, direction, and effectiveness of the overall QA program has sufficient authority to effectively implement

responsibilities. This position is to be sufficiently free from cost and schedule responsibilities. Qualification requirements for this individual are established in a position description which includes the following prerequisites:

a. Management experience through assignments to responsible positions.

b. Knowledge of QA regulations, policies, practices, and standards.

c. Experience working in QA or related activity in reactor design, construction, or operation or in a similar high technological industry.

The qualifications of the QA Manager should be at least equivalent to those described in Section 4.4.5 of ANSI/ANS-3.1-1978, "Selection and Training of Nuclear Power Plant Personnel," as endorsed by the regulatory positions in Regulatory Guide 1.8.

1C3. The person at the construction site responsible for directing and managing the site QA program is identified by position and has appropriate organizational position, responsibilities, and authority to exercise proper control over the QA program. This individual is free from non-QA duties and can thus give full attention to assuring that the QA program at the plant site is being effectively implemented.

Activities related to Quality Assurance Program (17.1.2) are acceptable if:

2A1. The scope of the QA program includes:

a. A commitment that activities affecting structures, systems, and components important to safety will be subject to the applicable controls of the QA program. The structures, systems, components, and related consumables covered by the QA program are identified (QA list) in Section 3.2.1 of the SAR.*

b. A commitment that the preoperational test program will be conducted in accordance with the QA program and a description of how the QA program will be applied.

c. A commitment that the development, control, and use of computer code programs will be conducted in accordance with the QA program and a description of how the QA program will be applied.

---

* Rulemaking is currently underway to clarify the requirement that structures, systems, and components important to safety as derived from the General Design Criteria of Appendix A to 10 CFR Part 50 shall be subjected to the pertinent requirements of the quality assurance criteria of Appendix B to 10 CFR 50. Until this rulemaking process is completed, staff reviewers should assure that the applicant's list of structures, systems, and components includes all those items necessary to prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public as stated in the Introduction to Appendix B. Guidance for identifying such items is provided in Regulatory Guide 1.29.

d. The identification of fire protection in SRP Section 9.5.1 as a system covered by the QA program or identification of the QA controls for fire protection. These controls are reviewed and accepted using the guidelines contained in BTP ASB 9.5-1 and 10 CFR Part 50 Appendix B as appropriate.

e. A commitment that special equipment, environmental conditions, skills, or processes will be provided as necessary.

2A2. A brief summary of the company's corporate QA policies is given.

2B1. a. Provisions are established to assure that quality-affecting procedures required to implement the QA program are consistent with QA program commitments and corporate policies and are properly documented, controlled, and made mandatory through a policy statement or equivalent document signed by the responsible official.

b. The QA organization reviews and documents concurrence with these quality-related procedures.

c. The organizational group or individual having responsibility for the policy statement should be identified.

d. The quality affecting procedural controls of the principal contractors should be provided for the applicant's review with documented agreement of acceptance prior to initiation of activities affected by the program.

2B2. Provisions are included for notifying NRC of changes (1) for review and acceptance in the accepted description of the QA program as presented or referenced in the SAR or SSAR prior to implementation, and (2) in organizational elements within 30 days after announcement. (Note - editorial changes or personnel reassignments of a non-substantive nature do not require NRC notification).

2B3. The applicant (and the principal contractors) commits to comply with the regulatory position in the appropriate issue of the Regulatory Guides listed in Subsection V; to comply with 10 CFR Part 50, §50.55a; to conduct activities under 10 CFR Part 50, §50.55(e) in accordance with the QA program; and to comply with 10 CFR Part 50 Appendix A, General Design Criterion 1. For systems, components, and structures covered by the ASME Code Section III (Classes 1, 2 and 3), the quality assurance code requirements should be supplemented by the specific guidance addressed in the regulatory positions of the applicable Regulatory Guides. The commitment identifies the Regulatory Guides and ANSI standard by number, title, and revision or date. Any alternatives or exceptions are clearly identified and supporting information presented in the docket. QA Regulatory Guides should be addressed which have an implementation date prior to the submittal or docket date of the QA program description.

Although primary responsibility for Regulatory Guides 1.26 and 1.29 is assigned to ASB (SRP Sections 3.2.1 and 3.2.2), their use as acceptance criteria in this SRP section is necessary to assure that

adequate quality assurance requirements are specified for systems, components, and structures addressed by those guides.

The QA organization and the necessary technical organizations participate early in the QA program definition stage to determine and identify the extent QA controls are to be applied to specific structures, systems, and components. This effort involves applying a defined graded approach to certain structures, systems, and components in accordance with their importance to safety and affects such disciplines as design, procurement, document control, inspection tests, special processes, records, audits, and others described in 10 CFR Part 50, Appendix B.

2B4. Existing or proposed QA procedures are identified reflecting that Regulatory Guides listed in subsection VI, General Design Criterion 1 of Appendix A to 10 CFR Part 50, 10 CFR Part 50, §50.55a, and each criterion of 10 CFR Part 50, Appendix B will be met by documented procedures. In addition, activities conducted under 10 CFR Part 50, §50.55(e) shall conform to the requirement of the QA program.

2B5. A description is provided that emphasizes how the docketed QA program description, particularly the 10 CFR Part 50 regulations and Regulatory Guides listed in subsection V, will be properly carried out.

2C1. A description is provided of how management (above or outside the QA organization) regularly assesses the scope, status, adequacy, and compliance of the QA program to 10 CFR Part 50, Appendix B. These measures should include:

a. Frequent contact with program status through reports, meetings, and/or audits.

b. Performance of an annual assessment preplanned and documented. Corrective action is identified and tracked.

2C2. Quality-related activities (such as design, procurement, and site investigation) initiated prior to formal NRC acceptance of the QA program are controlled under a QA program in accordance with this SRP and, accordingly, with the requirements of 10 CFR Part 50, Appendix B. Approved procedures and a sufficient number of trained personnel should be available to implement the applicable portion of the QA program prior to the initiation of the activity.

2C3. A summary description is provided on how responsibilities and control of quality-related activities are transferred from the principal contractors to the applicant during the phaseout of design and construction and during preoperational testing and plant turnover.

2D. Indoctrination, training, and qualification programs are established such that:

a. Personnel responsible for performing quality-affecting activities are instructed as to the purpose, scope, and implementation of the quality-related manuals, instructions, and procedures.

b. Personnel verifying activities affecting quality are trained and qualified in the principles, techniques, and requirements of the activity being performed.

c. For formal training and qualification programs, documentation includes the objective, content of the program, attendees, and date of attendance.

d. Proficiency tests are given to those personnel performing and verifying activities affecting quality, and acceptance criteria are developed to determine if individuals are properly trained and qualified.

e. Certificate of qualifications clearly delineates (a) the specific functions personnel are qualified to perform and (b) the criteria used to qualify personnel in each function.

f. Proficiency of personnel performing and verifying activities affecting quality is maintained by retraining, reexamining, and/or recertifying as determined by management or program commitment.

g. The description of the training program provisions listed above satisfies the regulatory position in Regulatory Guide 1.58.

Activities related to Design Control (17.1.3) are acceptable if:

3A. The scope of the design control program includes design activities associated with the preparation and review of design documents including the correct translation of applicable regulatory requirements and design bases into design, procurement and procedural documents. Included in the scope are such activities as field design engineering; physics, seismic, stress, thermal, hydraulic, radiation, and the SAR accident analyses; associated computer programs; compatibility of materials; accessibility for inservice inspection, maintenance, and repair; and quality standards.

3B. Organizational responsibilities are described for preparing, reviewing, approving, and verifying design documents such as system descriptions, design input and criteria, design drawings, design analyses, computer programs, specifications, and procedures.

3C1. Errors and deficiencies in approved design documents, including design methods (such as computer codes), that could adversely affect structures, systems, and components important to safety are documented; and action is taken to assure that all errors and deficiencies are corrected.

3C2. Deviations from specified quality standards are identified and procedures are established to ensure their control.

3D. Internal and external design interface controls, procedures, and lines of communication among participating design organizations and across technical disciplines are established and described for the review, approval, release, distribution, and revision of documents involving design interfaces to assure structures, systems, and

components are compatible geometrically, functionally, and with processes and environment.

3E1. Procedures are established and described requiring a documented check to verify the dimensional accuracy and completeness of design drawing and specifications.

3E2. Procedures are established and described requiring that design drawings and specifications be reviewed by the QA organization to assure that the documents are prepared, reviewed, and approved in accordance with company procedures and that the documents contain the necessary quality assurance requirements such as inspection and test requirements, acceptance requirements, and the extent of documenting inspection and test results.

3E3. Guidelines or criteria are established and described for determining the method of design verification (design review, alternate calculations, or test).

3E4. Procedures are established and described for design verification activities which assure the following:

a. The verifier is qualified and is not directly responsible for the design (i.e., neither the performer or his immediate supervisor). In exceptional circumstances, the designer's immediate supervisor can perform the verification provided:

(1) The supervisor is the only technically qualified individual.

(2) The need is individually documented and approved in advance by the supervisor's management.

(3) QA audits cover frequency and effectiveness of use of supervisors as design verifiers to guard against abuse.

b. Design verification, if other than by qualification testing of a prototype or lead production unit, is completed prior to release for procurement, manufacturing, construction or to another organization for use in other design activities. In those cases where this timing cannot be met, the design verification may be deferred, providing that the justification for this action is documented and the unverified portion of the design output document and all design output documents, based on the unverified data, are appropriately identified and controlled. Construction site activities associated with a design or design change should not proceed without verification past the point where the installation would become irreversible (i.e., require extensive demolition and rework). In all cases, the design verification should be complete prior to fuel load for a plant under construction, or in the case of an operating plant, prior to relying upon the component, system, or structure to perform its function.

c. Procedural control is established for design documents that reflect the commitments of the SAR; this control differentiates between documents that receive formal design verification by

interdisciplinary or multi-organizational teams and those which can be reviewed by a single individual (a signature and date is acceptable documentation for personnel certification). Design documents subject to procedural control include, but are not limited to, specifications, calculations, computer programs, system descriptions, SAR when used as a design document, and drawings including flow diagrams, piping and instrument diagrams, control logic diagrams, electrical single line diagrams, structural systems for major facilities, site arrangements, and equipment locations. Specialized reviews should be used when uniqueness or special design considerations warrant.

d. The responsibilities of the verifier, the areas and features to be verified, the pertinent considerations to be verified, and the extent of documentation are identified in procedures.

3E3. The following provisions are included if the verification method is only by test:

a. Procedures provide criteria that specify when verification should be by test.

b. Prototype, component or feature testing is performed as early as possible prior to installation of plant equipment, or prior to the point when the installation would become irreversible.

c. Verification by test is performed under conditions that simulate the most adverse design conditions as determined by analysis.

3E4. Procedures are established to assure that verified computer codes are certified for use and that their use is specified.

3F1. Design and specification changes, including fields changes, are subject to the same design controls that were applicable to the original design.

3F2. The description of the design control provisions satisfies the criteria of Regulatory Guide 1.64.

Activities related to Procurement Document Control (17.1.4) are acceptable if:

4A1. Procedures are established for the review of procurement documents to determine that quality requirements are correctly stated, inspectable, and controllable; there are adequate acceptance and rejection criteria; and procurement documents have been prepared, reviewed, and approved in accordance with QA program requirements. To the extent necessary, procurement documents should require contractors and subcontractors to provide an acceptable quality assurance program. The review and documented concurrence of the adequacy of quality requirements stated in procurement documents is performed by independent personnel trained and qualified in QA practices and concepts.

4A2. Procedures are established to assure that procurement documents identify applicable regulatory, technical, administrative, and

reporting requirements; drawings; specifications; codes and industrial standards; test and inspection requirements; and special process instructions that must be complied with by suppliers.

4B1. Organizational responsibilities are described for (1) procurement planning; (2) the preparation, review, approval, and control of procurement documents; (3) supplier selection; (4) bid evaluations; and (5) review and concurrence of supplier QA programs prior to initiation of activities affected by the program. The involvement of the QA organization is described.

4B2. The description of the procurement document control provisions listed above satisfies the regulatory position in Regulatory Guide 1.123.

Activities related to Instructions, Procedures, and Drawings (17.1.5) are acceptable if:

5A. Organizational responsibilities are described for assuring that activities affecting quality are (1) prescribed by documented instructions, procedures, and drawings and (2) accomplished through implementation of these documents.

5B. Procedures are established to assure that instructions, procedures, and drawings include quantitative (such as dimensions, tolerances, and operating limits) and qualitative (such as workmanship samples) acceptance criteria for determining that important activities have been satisfactorily accomplished.

Activities related to Document Control (17.1.6) are acceptable if:

6A1. The scope of the document control program is described, and the types of controlled documents are identified. As a minimum, controlled documents include:

a. Design documents (e.g., calculations, drawings, specifications, analyses) including documents related to computer codes.

b. Procurement documents.

c. Instructions and procedures for such activities as fabrication, construction, modification, installation, test, and inspection.

d. As-built documents.

e. Quality assurance and quality control manuals and quality-affecting procedures.

f. Topical reports.

g. SAR.

h. Nonconformance reports.

6A2. Procedures for the review, approval, and issuance of documents and changes thereto are established and described to assure technical

adequacy and inclusion of appropriate quality requirements prior to implementation. The QA organization, or an individual other than the person who generated the document but qualified in quality assurance, reviews and concurs with these documents with regards to QA-related aspects.

6A3. Procedures are established to assure that changes to documents are reviewed and approved by the same organizations that performed the initial review and approval or by other qualified responsible organizations delegated by the applicant.

6A4. Procedures are established to assure that documents are available at the location where the activity will be performed prior to commencing the work.

6B1. Procedures are established and described to assure that obsolete or superseded documents are removed and replaced by applicable revisions in work areas in a timely manner.

6B2. A master list or equivalent document control system is established to identify the current revision of instructions, procedures, specifications, drawings, and procurement documents. When such a list is used, it should be updated and distributed to predetermined responsible personnel.

6C1. Procedures are established and described to provide for the preparation of as-built drawings and related documentation in a timely manner to accurately reflect the actual plant design.

Activities related to Control of Purchased Material, Equipment, and Services (17.1.7) are acceptable if:

7A1. Organizational responsibilities are described for the control of purchased material, equipment, and services including interfaces between design, procurement, and QA organizations.

7A2. Verification of suppliers' activities during fabrication, inspection, testing, and shipment of materials, equipment, and components is planned and performed with QA organization participation in accordance with written procedures to assure conformance to the purchase order requirements. These procedures, as applicable to the method of procurement, provide for:

a. Specifying the characteristics or processes to be witnessed, inspected or verified, and accepted; the method of surveillance and the extent of documentation required; and those responsible for implementing these procedures.

b. Audits, surveillance, or inspections which assure that the supplier complies with the quality requirements.

7A3. Selection of suppliers is documented and filed. If an LCVIP letter of confirmation or the "CASE" Register is used to establish the qualifications of the supplier, the documentation should identify the "letter" or "audit" used.

7A4. Procurement of spare or replacement parts for structures, systems, and components important to safety is subject to present QA program controls, to codes and standards, and to technical requirements equal to or better than the original technical requirements, or as required to preclude repetition of defects.

7B1. Receiving inspection is performed to assure:

a. The material, component, or equipment is properly identified and corresponds to the identification on the purchase document and the receiving documentation.

b. Material, components, equipment, and acceptance records satisfy the inspection instructions prior to installation or use.

c. Specified inspection, test and other records, (such as certificates of conformance attesting that the material, components, and equipment conform to specified requirements) are available at the nuclear power plant prior to installation or use.

7B2. Items accepted and released are identified as to their inspection status prior to forwarding them to a controlled storage area or releasing them for installation or further work.

7B3. The supplier furnishes the following records to the purchaser:

a. Documentation that identifies the purchased item and the specific procurement requirements (e.g., codes, standards, and specifications) met by the item.

b. Documentation identifying any procurement requirements that have not been met.

c. A description of those nonconformances from the procurement requirements dispositioned "accept as is" or "repair."

The review and acceptance of these documents should be described in the purchaser's QA program.

7B4. For commercial "off-the-shelf" items where specific quality assurance controls appropriate for nuclear applications cannot be imposed in a practicable manner, special quality verification requirements shall be established and described to provide the necessary assurance of an acceptable item by the purchaser.

7B5. Suppliers' certificates of conformance are periodically evaluated by audits, independent inspections, or tests to assure they are valid and the results documented.

7B6. The description of the control of procurement provisions listed above satisifies the regulatory position in Regulatory Guide 1.38 and Regulatory Guide 1.123.

Activities related to Identification and Control of Materials, Parts, and Components (17.1.8) are acceptable if:

8A. Controls are established and described to identify and control materials (including consumables), parts, and components including partially fabricated subassemblies. The description should include organizational responsibilities.

8B1. Procedures are established which assure that identification is maintained either on the item or on records traceable to the item to preclude use of incorrect or defective items.

8B2. Identification of materials and parts important to the function of structures, systems, and components important to safety can be traced to the appropriate documentation such as drawings, specifications, purchase orders, manufacturing and inspection documents, deviation reports, and physical and chemical mill test reports.

8B3. Correct identification of material, parts, and components is verified and documented prior to release for fabrication, assembling, shipping, and installation.

Activities related to Control of Special Processes (17.1.9) are acceptable if:

9A1. The criteria for determining those processes that are controlled as special processes are described. As complete a listing as possible of special processes, which are generally those processes where direct inspection is impossible or disadvantageous, should be provided. Some examples are welding, heat treating, NDT, and chemical cleaning.

9A2. Organizational responsibilities including those for the QA organization are described for qualification of special processes, equipment, and personnel.

9B1. Procedures, equipment, and personnel associated with special processes are qualified and are in conformance with applicable codes, standards, QA procedures, and specifications. The QA organization is involved in the qualification activities to assure they are satisfactorily performed.

9B2. Procedures are established for recording evidence of acceptable accomplishment of special processes using qualified procedures, equipment, and personnel.

9B3. Qualification records of procedures, equipment, and personnel associated with special processes are established, filed, and kept current.

Activities related to Inspection (17.1.10) are acceptable if:

10A. The scope of the inspection program is described that indicates an effective inspection program has been established. Program procedures provide criteria for determining the accuracy requirements of inspection equipment and criteria for determining when inspections are

required or define how and when inspections are performed. The QA organization participates in the above functions.

10B1. Organizational responsibilities for inspection are described. Individuals performing inspections are other than those who performed or directly supervised the activity being inspected and do not report directly to the immediate supervisors who are responsible for the activity being inspected. If the individua performing inspections are not part of the QA organization, thr .spection procedures, personnel qualification criteria, and independence from undue pressure such as cost and schedule should be reviewed and found acceptable by the QA organization prior to the initiation of the activity.

10B2. A qualification program for inspectors (including NDT personnel) is established and documented, and the qualifications and certifications of inspectors are kept current.

10C1. Inspection procedures, instructions, or checklists provide for the following:

a. Identification of characteristics and activities to be inspected.

b. A description of the method of inspection.

c. Identification of the individuals or groups responsible for performing the inspection operation in accordance with the provisions of item 10B1.

d. Acceptance and rejection criteria.

e. Identification of required procedures, drawings and specifications and revisions.

f. Recording inspector or data recorder and the results of the inspection operation.

g. Specifying necessary measuring and test equipment including accuracy requirements.

10C2. Procedures are established and described to identify, in pertinent documents, mandatory inspection hold points beyond which work may not proceed until inspected by a designated inspector.

10C3. Inspection results are documented, evaluated and their acceptability determined by a responsible individual or group.

Activities related to Test Control (17.1.11) are acceptable if:

11A1. The description of the scope of the test control program indicates an effective test program has been established for tests including proof tests prior to installation and preoperational tests. Program procedures provide criteria for determining the accuracy requirements of test equipment and criteria for determining when a test is required or how and when testing activities are performed.

11B1. Test procedures or instructions provide as required for the following:

a. The requirements and acceptance limits contained in applicable design and procurement documents.

b. Instructions for performing the test.

c. Test prerequisites such as calibrated instrumentation, adequate test equipment and instrumentation including their accuracy requirements, completeness of item to be tested, suitable and controlled environmental conditions, and provisions for data collection and storage.

d. Mandatory inspection hold points for witness by owner, contractor, or inspector (as required).

e. Acceptance and rejection criteria.

f. Methods of documenting or recording test data and results.

g. Provisions for assuring test prerequisites have been met.

11C1. Test results are documented, evaluated, and their acceptability determined by a responsible individual or group.

Activities related to Control of Measuring and Test Equipment (17.1.12) are acceptable if:

12.1 The scope of the program for the control of measuring and test equipment is described and the types of equipment to be controlled are established. This information indicates an effective calibration program has been established.

12.2 QA and other organizations' responsibilities are described for establishing, implementing, and assuring effectiveness of the calibration program.

12.3 Procedures are established and described for calibration (technique and frequency), maintenance, and control of the measuring and test equipment (instruments, tools, gages, fixtures, reference and transfer standards, and nondestructive test equipment) that is used in the measurement, inspection, and monitoring of structures, systems, and components. The review and documented concurrence of these procedures is described and the organization responsible for these functions is identified.

12.4 Measuring and test equipment is identified and traceable to the calibration test data.

12.5 Measuring and test equipment is labeled or tagged or "otherwise controlled" to indicate due date of the next calibration. The method of "otherwise controlled" should be described.

12.6 Measuring and test equipment is calibrated at specified intervals based on the required accuracy, purpose, degree of usage, stability characteristics, and other conditions affecting the measurement.

Calibration of this equipment should be against standards that have an accuracy of at least four times the required accuracy of the equipment being calibrated or, when this is not possible, have an accuracy that assures the equipment being calibrated will be within required tolerance and that the basis of acceptance is documented and authorized by responsible management. The management authorized to perform this function is identified.

12.7 Calibrating standards have greater accuracy than standards being calibrated. Calibrating standards with the same accuracy may be used if it can be shown to be adequate for the requirements and the basis of acceptance is documented and authorized by responsible management. The management authorized to perform this function is identified.

12.8 Reference and transfer standards are traceable to nationally recognized standards; where national standards do not exist, provisions are established to document the basis for calibration.

12.9 Measures are taken and documented to determine the validity of previous inspections performed and the acceptability of items inspected or tested since the last calibration when measuring and test equipment is found to be out of calibration. Inspections or tests are repeated on items determined to be suspect.

Activities related to Handling, Storage, and Shipping (17.1.13) are acceptable if:

13.1 Special handling, preservation, storage, cleaning, packaging, and shipping requirements are established and accomplished by suitably trained individuals in accordance with predetermined work and inspection instructions.

13.2 Procedures are established and described to control the cleaning, handling, storage, packaging, and shipping of materials, components, and systems in accordance with design and procurement requirements to preclude damage, loss, or deterioration by environmental conditions such as temperature or humidity.

13.3 The description of the control of handling, storage, and shipping listed above satisfies the regulatory position in Regulatory Guide 1.38.

Activities related to Inspection, Test, and Operating Status (17.1.14) are acceptable if:

14.1 Procedures are established to indicate the inspection, test, and operating status of structures, systems, and components throughout fabrication, installation, and test.

14.2 Procedures are established and described to control the application and removal of inspection and welding stamps and status indicators such as tags, markings, labels, and stamps.

14.3 Procedures are established and described to control altering the sequence of required tests, inspections, and other operations important to safety. Such actions should be subject to the same controls as the original review and approval.

14.4 The status of nonconforming, inoperative, or malfunctioning structures, systems, and components is documented and identified to prevent inadvertent use. The organization responsible for this function is identified.

Activities related to Nonconforming Materials, Parts, or Components (17.1.15) are acceptable if:

15.1 Procedures are established and described for identification, documentation, segregation, review, disposition, and notification to affected organizations of nonconforming materials, parts, components and as applicable to services (including computer codes) if disposition is other than to scrap. The procedures provide identification of authorized individuals for independent review of nonconformances, including disposition and closeout.

15.2 QA and other organizational responsibilities are described for the definition and implementation of activities related to nonconformance control. This includes identifying those individuals or groups with authority for the disposition of nonconforming items.

15.3 Documentation identifies the nonconforming item; describes the nonconformance, the disposition of the nonconformance, and the inspection requirements; and includes signature approval of the disposition. Nonconformances are corrected or resolved prior to the initiation of the preoperational test program on the item.

15.4 Reworked, repaired, and replacement items are inspected and tested in accordance with the original inspection and test requirements or acceptable alternatives.

15.5 Nonconformance reports are periodically analyzed by the QA organization to show quality trends, and the significant results are reported to upper management for review and assessment.

Activities related to Corrective Action (17.1.16) are acceptable if:

16.1 Procedures are established and described indicating an effective corrective action program has been established. The QA organization reviews and documents concurrence with the procedures.

16.2 Corrective action is documented and initiated following the determination of a condition adverse to quality (such as a nonconformance, failure, malfunction, deficiency, deviation, and defective material and equipment) to preclude recurrence. The QA organization is involved in the documented concurrence of the adequacy of the corrective action.

16.3 Followup action is taken by the QA organization to verify proper implementation of corrective action and to close out the corrective action in a timely manner.

16.4 Significant conditions adverse to quality, the cause of the conditions, and the corrective action taken to preclude repetition are documented and reported to immediate management and upper levels of management for review and assessment.

Activities related to Quality Assurance Records (17.1.17) are acceptable if:

17.1 The scope of the records program is described. QA records include results of reviews, inspections, tests, audits, and material analyses; monitoring of work performance; qualification of personnel, procedures, and equipment; and other documentation such as drawings, specifications, procurement documents, calibration procedures and reports; nonconformance reports; and corrective action reports.

17.2 QA and other organizations are identified and their responsibilities are described for the definition and implementation of activities related to QA records.

17.3 Inspection and test records contain the following where applicable:

a. A description of the type of observation.

b. The date and results of the inspection or test.

c. Information related to conditions adverse to quality.

d. Inspector or data recorder identification.

e. Evidence as to the acceptability of the results.

f. Action taken to resolve any discrepancies noted.

17.4 Suitable facilities for the storage of records are described and satisfy the regulatory position given in Regulatory Guide 1.88 (endorses N45.2.9). Alternatives to the fire protection rated provisions are acceptable if records storage facilities conform to NFPA No. 232 Class 1 for permanent-type records and that the 2-hour fire rating requirement contained in the proposed N45.2.9 standard is met by applicants in any one of the following three ways. Specifically, (1) a 2-hour vault meeting NFPA No. 232; (2) 2-hour rated file containers meeting NFPA No. 232 (Class B); or (3) a 2-hour rated fire resistant file room meeting NFPA No. 232 if the following additional provisions are provided.

1. Early warning fire detection and automatic fire suppression should be provided, with electronic supervision at a constantly attended central station.

2. Records should be stored in fully enclosed metal cabinets. Records should not be permitted on open steel shelving. No storage of records should be permitted on the floor of the facility. Adequate access and aisle ways should be maintained at all times throughout the facility.

3. Work not directly associated with records storage or retrieval should be prohibited within the records storage facility. Examples of such prohibited activities include but are not limited to: records reproduction, film developing, and fabrication of microfiche cards.

4. Smoking and eating/drinking should be prohibited throughout the records storage facility.

5. Ventilation, temperature, and humidity control equipment should be protected inside with standard fire-door dampers where they penetrate fire barriers bounding the storage facility.

17.5 The description of the control of records provisions listed above satisfies the regulatory position of Regulatory Guide 1.88.

Activities related to Audits (17.1.18) are acceptable if:

18A1. Audits to assure that procedures and activities comply with the overall QA program are performed by:

a. The QA organization to provide a comprehensive independent verification and evaluation of quality-related procedures and activities.

b. The applicant (and principal contractors) to verify and evaluate the QA programs, procedures, and activities of suppliers.

18A2. An audit plan is prepared identifying audits to be performed, their frequencies, and schedules. Audits should be regularly scheduled based upon the status and safety importance of the activities being performed and are initiated early enough to assure effective QA during design, procurement, manufacturing, construction, installation, inspection, and testing.

18A3. Audits include an objective evaluation of quality-related practices, procedures, instructions; activities and items; and review of documents and records to ensure that the QA program is effective and properly implemented.

18A4. Provisions are established requiring that audits be performed in all areas where the requirements of Appendix B to 10 CFR Part 50 are applicable. Areas which are often neglected but should be included are activities associated with:

a. The determination of site features which affect plant safety (e.g., core sampling, site and foundation preparation, and methodology). (PSAR only).

b. The preparation, review, approval, and control of early procurements. (PSAR only).

c. Indoctrination and training programs.

d. Interface control among the applicant and the principal contractors.

e. Corrective action, calibration, and nonconformance control systems.

f. SAR and SSAR commitments.

g. Activities associated with computer codes.

18B1. Audit data are analyzed by the QA organization and the resulting reports indicating any quality problems and the effectiveness of the QA program, including the need for reaudit of deficient areas, are reported to management for review and assessment.

18B2. Audits are performed in accordance with pre-established written procedures or checklists and conducted by trained personnel having no direct responsibilities in the areas being audited.

18B3. The description of the conduct of audit provisions satisfies the regulatory position in Regulatory Guides 1.144 and 1.146.

III. REVIEW PROCEDURES

Each element of the QA program description will be reviewed against the acceptance criteria described in subsection II, including the regulations, Regulatory Guides, and Branch Technical Position listed in subsection V. QAB will interface with the secondary review branches to assure that they have documented to the QAB by memo the acceptability of the identification of structures, systems, and components covered by the QA program (Q-List). QAB will process the necessary requests for additional information to the applicant and coordinate the response with the appropriate branches for acceptance. Changes to the QA program will be evaluated to assure at a minimum that such changes have not degraded the previously approved program. Consideration should be given to the current regulatory position in the area of the change in determining acceptability of the change. The reviewer's judgment during the review is to be based on an assessment of the material presented, the similarity of the material to that recently reviewed on other plants, and whether items of special safety significance are involved. Any exceptions or alternatives to this SRP section, including the regulations and regulatory positions presented in the Regulatory Guides in subsection V, will be carefully reviewed to assure that they are clearly defined and that an adequate basis exists for acceptance.

The acceptability of the QA program is determined by the following review procedures:

1. The QA program description is reviewed in detail to determine if each of the criteria of 10 CFR Part 50, Appendix B has been acceptably addressed and if there is an adequate commitment to comply with the regulations and regulatory positions in the appropriate issue of the Regulatory Guides in subsection V, as identified by number, title, revision or date. The QA program description is also reviewed to assure that the applicant's approach to meeting the QA criteria and commitments is acceptable.

2. The measures described to implement 10 CFR Part 50, Appendix B are evaluated for:

   a. Technical acceptability (i.e., do they meet the Regulations and Regulatory Guides?)

b. Workability (i.e., do they seem to fit into an overall plan of action that can be implemented?)

c. Management support (i.e., do QA program measures have adequate review, approval, and endorsement of management?)

This evaluation is based primarily on the acceptance criteria contained in subsection II.

3. The duties, responsibility, and authority of personnel performing QA functions are reviewed to assure they provide sufficient independence to effectively perform these functions.

4. Through review of information provided, meetings with the applicant, by review of the acceptability of QA program and plant activities including performance and capability of personnel, and by review of the Office of Inspection and Enforcement position statement and inspection reports, a judgment is made of the applicant's capability to carry out its QA responsibilities.

5. Satisfaction with program commitments and descriptions of how the commitments will be met, organizational arrangements, and capabilities to fulfill QA requirements should lead to the conclusion of acceptability, as described in subsection IV.

IV. EVALUATION FINDINGS

The reviewer verifies that sufficient information has been provided and that his review is sufficiently complete and adequate to support conclusions of the following type to be included in the staff's Safety Evaluation Report:

Based on our detailed review and evaluation of the QA program description contained in the (topical report or SAR) for (nuclear facility), we conclude that:

1. The organizations and persons performing QA functions have the required independence and authority to effectively carry out the QA program without undue influence from those directly responsible for costs and schedules.

2. The QA program describes requirements, procedures, and controls that, when properly implemented, comply with the requirements of Appendix B to 10 CFR Part 50 with the requirements of 10 CFR Part 50, §50.55a and §55(e); with the criteria contained in SRP Section 17.1; and with the regulatory positions presented in the following Regulatory Guides.

| Reg. Guide/ANSI Std. | Title | Revision or Date |
|---|---|---|

A brief description of the applicant's QA program is provided highlighting the more important aspects of the program.

3. The QA program covers activities affecting structures, systems, and components important to safety as identified in the PSAR.

Accordingly, the staff concludes that the applicant's description of the QA program is in compliance with applicable NRC regulations and industry standards and can be implemented for the (specify) phases of (specify application).

## V. IMPLEMENTATION

The following is intended to provide guidance to applicants and licensees regarding the NRC staff's plan for using this SRP Section.

Except in those cases in which the applicant proposes an acceptable alternative method for complying with specified portions of the Commission's regulations, the method described herein will be used by the staff in its evaluation of conformance with Commission regulations.

Implementation schedules for conformance to parts of the method discussed herein are contained in the referenced guides and NUREGs.

## VI. REFERENCES


1. 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants."

2. 10 CFR Part 50, §50.55a, "Codes and Standards."

3. 10 CFR Part 50, §50.55(e), "Conditions of Construction Permits" (reporting significant QA deficiencies).

4. 10 CFR Part 50, §50.34(a.7), "Contents of Application; Technical Information" (Preliminary Safety Analysis QA program description).

5. 10 CFR Part 50, Appendix A, "General Design Criteria for Nuclear Power Plants."

6. Regulatory Guide 1.8, "Personnel Selection and Training" (endorses ANSI/ANS 3.1).

7. Regulatory Guide 1.26, "Quality Group Classification, and Standards for Water, Steam, and Radioactive Waste Containing Components of Nuclear Power Plants."

8. Regulatory Guide 1.28, "Quality Assurance Program Requirements (Design and Construction)" (endorses N45.2).

9. Regulatory Guide 1.29, "Seismic Design Classification."

10. Regulatory Guide 1.30, "Quality Assurance Requirements for the Installation, Inspection, and Testing of Instrumentation and Electric Equipment" (endorses N45.2.4).

11. Regulatory Guide 1.37, "Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants" (endorses N45.2.1).

12. Regulatory Guide 1.38, "Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Water-Cooled Nuclear Power Plants" (endorses N45.2.2).

13. Regulatory Guide 1.39, "Housekeeping Requirements for Water-Cooled Nuclear Power Plants" (endorses N45.2.3).

14. Regulatory Guide 1.58, "Qualification of Nuclear Power Plant Inspection, Examination, and Testing Personnel" (endorses N45.2.6).

15. Regulatory Guide 1.64, "Quality Assurance Requirements for the Design of Nuclear Power Plants" (endorses N45.2.11).

16. Regulatory Guide 1.74, "Quality Assurance Terms and Definitions" (endorses N45.2.10).

17. Regulatory Guide 1.88, "Collection, Storage, and Maintenance of Nuclear Power Plant Quality Assurance Records" (endorses N45.2.9).

18. Regulatory Guide 1.94, "Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete and Structural Steel During the Construction Phase of Nuclear Power Plants" (endorses N45.2.5).

19. Regulatory Guide 1.116, "Quality Assurance Requirements for Installation, Inspection, and Testing of Mechanical Equipment and Systems" (endorses N45.2.8).

20. Regulatory Guide 1.123, "Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants" (endorses N45.2.13).

21. Regulatory Guide 1.144, "Auditing of Quality Assurance Programs for Nuclear Power Plants" (endorses N45.2.12).

22. Regulatory Guide 1.146, "Qualification of Quality Assurance Program Audit Personnel for Nuclear Power Plants" (endorses N45.2.23).

23. Branch Technical Position (BTP) ASB 9.5-1 (attached to SRP Section 9.5.1).

U.S. NUCLEAR REGULATORY COMMISSION

# STANDARD REVIEW PLAN

OFFICE OF NUCLEAR REACTOR REGULATION

## 17.2 QUALITY ASSURANCE DURING THE OPERATIONS PHASE

REVIEW RESPONSIBILITIES

Primary - Quality Assurance Branch (QAB)

Secondary - Mechanical Engineering Branch
Instrumentation & Control Systems Branch
Power Systems Branch
Accident Evaluation Branch
Radiological Assessment Branch
Hydrologic & Geotechnical Engineering Branch
Containment Systems Branch

### I. AREAS OF REVIEW

QAB reviews and evaluates the applicant's operational quality assurance (QA) program as described in the FSAR. The review at the operating license stage addresses both the "offsite" and "onsite" QA controls to be applied to those activities that may affect the quality of items important to safety during the operation, maintenance, and modification of a nuclear power plant. The review covers the QA controls to be applied to those activities (e.g., designing, constructing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, maintaining, modifying, operating, inspecting, and testing) that may affect the quality of structures, systems, and components important to safety. The secondary review branches review the listing of structures, systems, and components (QA list) covered by the QA program for their areas of review responsibility in accordance with 2A1 of this section of the Standard Review Plan and documents the acceptability of the listing including any items that should be added or clarified by memo to the QAB. The review by MEB in this regard also addresses the areas of review responsibility normally assigned to ASB, RSB, CEB, PSB (except electrical), and SEB.

The review extends to the determination of how the applicable requirements of the 18 criteria of Appendix B to 10 CFR Part 50 are satisfied by the proposed QA program.

Where an NRC-accepted QA topical report is referenced in the application, the referenced QA program is not re-reviewed except for conformance to the applicable staff positions in this SRP section and the Regulatory Guides in effect at the time of docketing the application.

The review will not involve an evaluation of the QA program for the design and construction phase and, therefore, the QAP description for design and construction should not be addressed in the FSAR except for a commitment for continued implementation of the PSAR QA program for the remaining design and construction activities and the preoperational test program or referenced as applicable for repair and modifications only during the operations phase. However, as desired, changes to the QA program for design and construction may be presented in the FSAR for staff review and approval. Staff review will only address the program changes.

The areas of review for this SRP section are the same as those described in SRP Section 17.1 except:

1. Organization (item 1) delete from part A: "including the applicant's organization and principal contractors (architect engineer, nuclear steam supply system vendor, constructor, and construction manager when other than the constructor)."

2. Audits (item 18) add a part C: "Provisions for the audit of operating activities important to safety independent of the operating organization."

## II. ACCEPTANCE CRITERIA

The applicant must establish a QA program for the operations phase, including activities such as operation, maintenance, and modification of the nuclear power plant, in accordance with Appendix B to 10 CFR Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." The QA program description presented in the FSAR must discuss how each criterion of Appendix B will be met. The acceptance criteria used by the QAB to evaluate the program are listed below. The acceptance criteria include commitments to comply with the regulatory positions presented in the appropriate issue of the Regulatory Guides including the requirements of ANSI Standard N45.2.12 and the Branch Technical Position listed in subsection V of SRP Section 17.1. Thus, these commitments constitute an integral part of the QA program description and requirements. Exceptions and alternatives to these acceptance criteria may be taken by applicants provided adequate justification is given; and the QAB review allows for considerable flexibility in defining methods and controls for satisfying pertinent regulations. When the QA program description meets the acceptance criteria of this SRP section or provides acceptable exceptions or alternatives, the program is considered to be in compliance with pertinent NRC regulations. The review will ascertain that the commitments and the description of how the commitments are implemented, to the extent necessary, are objective and stated in inspectable terms.

The Organization (SRP Section 17.2.1) elements responsible for the QA program are acceptable if:

1. The criteria described in 17.1.1* are satisfied except for:

*Refers to the acceptance criteria given in subsection II of SRP Section 17.1.

a. Item 1A4.

b. The organizational elements within the parenthesis in item 1A5 be expanded to include operations and maintenance.

c. The requirements that principal contractors describe QA responsibilities be deleted in Item 1A6.

d. The requirements that a QA position be identified for principal contractors as described in Item 1B1, be deleted.

e. "The person at the construction site responsible for directing and managing the site QA program..." described in Item IC3, be changed to "The person...responsible for...the onsite QA program," and continue on with remaining sentence starting with "has appropriate organizational...."

The Quality Assurance Program (SRP Section 17.2.2) description is acceptable if:

1. The criteria described in 17.1.2 are satisfied except for:

   a. Item 2A1b.

   b. The requirement for the principal contractors to provide a commitment to comply with the regulations and regulatory positions in the Regulatory Guides addressed in Item 2B3.

   c. Item 2C2.

   d. Item 2C3.

2. Provisions are established for assuring the QA program for operations is implemented at least 90 days prior to fuel loading.

3. Confirmation is provided to commit to continued implementation of the PSAR QA program for the remaining design and construction activities and the preoperational test program or an acceptable alternative is provided.

Activities related to Design Control (SRP Section 17.2.3) are acceptable if:

1. The criteria described in 17.1.3 are satisfied.

2. Measures are provided to assure that responsible plant personnel are made aware of design changes/modifications which may affect the performance of their duties.

Activities related to Procurement Document Control (17.2.4) are acceptable if:

1. The criteria described in 17.1.4 are satisfied.

Activities related to Instructions, Procedures, and Drawings (17.2.5) are acceptable if:

1. The criteria described in 17.1.5 are satisfied.

Activities related to Document Control (17.2.6) are acceptable if:

1. The criteria described in 17.1.6 are satisfied.

2. Maintenance, modification and inspection procedures are reviewed by qualified personnel knowledgeable in QA disciplines (normally the QA organization) to determine:

   a. The need for inspection, identification of inspection personnel, and documentation of inspection results.

   b. That the necessary inspection requirements, methods, and acceptance criteria have been identified.

Activities related to Control of Purchased Material, Equipment, and Services (17.2.7) are acceptable if:

1. The criteria described in 17.1.7 are satisfied.

Activities related to Identification and Control of Materials, Parts, and Components (17.2.8) are acceptable if:

1. The criteria described in 17.1.8 are satisfied.

Activities related to the Control of Special Processes (17.2.9) are acceptable if:

1. The criteria described in 17.1.9 are satisfied.

Activities related to Inspection (17.2.10) are acceptable if:

1. The criteria described in 17.1.10 are satisfied.

2. When inspections associated with normal operations of the plant (such as routine maintenance, surveillance, and tests) are performed by individuals other than those who performed or directly supervised the work, but are within the same group, the following controls are met:

   a. The quality of the work can be demonstrated through a functional test when the activity involves breaching a pressure retaining item.

   b. The qualification criteria for inspection personnel are reviewed and found acceptable by the QA organization prior to initiating the inspection.

Activities related to Test Control (17.2.11) are acceptable if:

1. The criteria described in 17.1.11 are satisfied.

Activities related to Control of Measuring and Test Equipment (17.2.12) are acceptable if:

1. The criteria described in 17.1.12 are satisfied.

Activities related to Handling, Storage, and Shipping (17.2.13) are acceptable if:

1. The criteria described in 17.1.13 are satisfied.

2. Provisions are described for the storage of chemicals, reagents (including control of shelf life), lubricants, and other consumable materials.

Activities related to Inspection, Test, and Operating Status (17.2.14) are acceptable if:

1. The criteria described in 17.1.14 are satisfied.

Activities related to Nonconforming Materials, Parts, or Components (17.2.15) are acceptable if:

1. The criteria described in 17.1.15 are satisfied.

Activities related to Corrective Action (17.2.16) are acceptable if:

1. The criteria described in 17.1.16 are satisfied.

Activities related to Quality Assurance Records (17.2.17) are acceptable if:

1. The criteria described in 17.1.17 are satisfied.

2. QA records include operating logs, maintenance and modification procedures, and related inspection results, reportable occurrences, and other records required by Technical Specifications.

Activities related to Audits (17.2.18) are acceptable if:

1. The criteria described in 17.1.18 are satisfied.

2. Where the "onsite" QA organization does not report to the "offsite" organization:

   a. The "offsite" QA organization conducts audits sufficient to verify adequacy of activities conducted by the "onsite" QA organization.

   b. The "offsite" QA organization reviews and concurs in the schedule and scope of audits performed by the "onsite" QA organization.

   c. Results of audits performed by the "onsite" QA organization are provided to the "offsite" QA organization for review and assessment.

III. REVIEW PROCEDURES

Same as SRP Section 17.1 except that the Office of Inspection & Enforcement (I&E) does not provide a position statement to QAB relative to their assessment of the QA program implementation for SER input. I&E provides this assessment to the Licensing Project Manager. QAB reviews a description of the I&E summary

of completed QA program activities to further determine that the facility has been designed and constructed in accordance with PSAR program commitments.

IV. EVALUATION FINDINGS

Same as SRP Section 17.1.

V. IMPLEMENTATION

Same as SRP Section 17.1.

VI. REFERENCES

Same as SRP Section 17.1 except replace item 8, Regulatory Guide 1.28, "Quality Assurance Program Requirements (Design and Construction)" (endorses N45.2) with Regulatory Guide 1.33, "Quality Assurance Program Requirements (Operation)" (endorses N18.7); replace 10 CFR Part 50, §50.34(a.7) with 10 CFR Part 50, §50.34 (b.6ii), "Final Safety Analysis Report"; and delete 10 CFR Part 50, §50.55(e), "Conditions of Construction Permits."

# Enclosure 4

# Comment Resolution

## RESOLUTION OF COMMENTS

| | | |
|---|---|---|
| **Source:** | A. C. Thadani, Director<br>DST, ADT, NRR | (No comment per telecon, 2/9/90) |
| **Source:** | J. E. Richardson, Director<br>DET, ADT, NRR | (No comment per memo to Spraul, 2/14/90) |
| **Source:** | C. E. Rossi, Director<br>DOEA, ADT, NRR | (No comment per memo to Spraul, 2/27/90) |
| **Source:** | B. K. Grimes, Director<br>DRIS, ADT, NRR | (Comments per memo to Roe, 2/26/90) |

| COMMENT | RESOLUTION |
|---|---|
| 1. Under acceptance criterion II.B.4, Procurement Control, add a new item as follows:<br><br>i. Appropriate controls should be established to ensure an effective dedication program to establish suitability of commercial grade items for installation in safety-related applications. The dedication process should include an engineering evaluation to identify the item's critical characteristics and to identify an acceptance process to ensure those critical characteristics are met. | 1. Control of commercial-grade items is addressed in item II.B.4.h which now reads: "Appropriate controls for the selection, determination of suitability for intended use (critical characteristics), evaluation, receipt, and quality evaluation of commercial-grade items are to be imposed to ensure that they will perform as designed." Also, the action specified in the comment is required by NRC's endorsement of EPRI NP-5652, "Guideline for the utilization of Commercial-Grade Items in Nuclear Safety-Related Applications (NCIG-07)," in Generic Letter 89-02. Section 2.3 of the EPRI document addresses critical characteristics. Therefore, Generic Letter 89-02 has been added to the references under VI.B, "Other Programmatic QA Guidance." |
| 2. Delete the second sentence from item 7A3 of Section 17.1 of the present SRP which references the CASE Register and LCVIP letters of confirmation. | 2. This had, in fact, been done, but it was not reflected in the SRP Comparison. The comparison has been revised to address the deletion. |

3. Under acceptance criterion II.B.1, Methodology, add a new item as follows:

d. The structures, systems, and components (SSC) to be covered by the quality assurance program shall be identified. The degree to which a graded quality assurance program is applied to an SSC shall be identified.

3. Item II.A.1.c requires that the QAPD includes criteria to identify the QA program scope in lieu of a list of items covered by the program. We do not believe such a list should be in the "top level policy document" (QAPD), but we do agree that such a list is required. To clarify this, a new sentence has been added to item II.A.1.c as follows: A list of items under the control of the quality assurance program is to be established and maintained.

The idea that the QAPD should identify "the degree to which a graded quality assurance program is applied" to different items constitutes a new SRP requirement. As such, it is not incorporated into Section 17.3.

4. NUREG-1055 concluded that the NRC "quality assurance efforts have focused on the form and paper at the expense of implementation and evaluating quality of completed work, and they should be reoriented to emphasize performance and effectiveness." The review of the QAPD should be augmented with an in-depth baseline assessment that addresses the translation of the QAPD into working level procedures, processes, and staffing implementation. The ongoing NRC assessment would be performed as part of the appropriate NRC inspection program. Section III should be augmented by the following:

4. Section III, REVIEW PROCEDURES, has been revised to read as follows:
"New QAPDs will be reviewed against the acceptance criteria described in Section II, including the applicant's commitment to the applicable references listed in Section VI. Any exceptions or alternatives to this SRP section, including the applicable references in Section VI, will be reviewed to ensure that they are defined and that an adequate basis exists for their acceptance. When required, the Performance and Quality Evaluation Branch will prepare a request for additional information for the applicant

"After the PQEB has completely reviewed the QAPD (or changes thereto) and determined the acceptability of the upper tier document with respect to the appropriate SRP Section 17 controls, an in-depth baseline implementation assessment shall be performed.

"The assessment will be performed by NRR and Regional personnel as appropriate. The interpretation and translation of the QAPD commitments into respective utility procedures, processes, and organizational staffing will be reviewed. The assessment will focus on the effectiveness of the QAPD implementation. The overall conclusion of QAPD acceptability will be based upon the QAPD review and implementation effectiveness assessment."

and review the response for acceptability.

"Changes to a QAPD previously accepted by the NRC will be reviewed to determine their acceptability. The changed QAPD will be compared against the previously accepted QAPD, its controls, and the appropriate controls in Chapter 17 of the Standard Review Plan to determine the acceptability of the changes. When required, the reviewing organization will prepare a request for additional information for the applicant and review the response for acceptability.

"Upon concluding that the QAPD describes an acceptable quality assurance program, the reviewing organization may request that an inspection be performed by NRR or Regional personnel as appropriate. The inspection will assess the applicant's interpretation and translation of the QAPD commitments into its procedures, processes, and organizational staffing. The inspection will focus on the effectiveness of the QAPD implementation.

"Through review of the information provided by the applicant and, as required, meetings with the applicant, review of applicable NRC inspection reports, and discussion with involved NRC inspectors, a judgment is made of the applicant's capability to carry out its QA responsibilities. The reviewer's satisfaction with the QA program commitments,

| | | |
|---|---|---|
| | | the description of how the commitments will be met, the organizational arrangements, and the capabilities to fulfill the QAPD should lead to the conclusion of acceptability as described in Section IV." |
| **Source:** | F. Congel, Director DREP, ADT, NRR | (No comment per telecon, 2/23/90) |
| **Source** | M. W. Hodges, Director DRS, Region I | (Comments per telecon, 3/7/90) |
| COMMENT | | RESOLUTION |
| 1. Change "nondestructive testing" to "nondestructive examination" in item II.B.11.a. | | 1. So changed. |
| 2. Add "vendor-supplied documents" to the list of documents in item II.B.14.b to be controlled within the scope of the document control program. | | 2. So changed. Note that this is a requirement of Generic Letters 83-28 and 90-03. |
| **Source:** | A. F. Gibson, Director DRS, Region II | (Comments per memo to Roe, 3/27/90) |
| COMMENT<br>Cover Letter | | RESOLUTION |
| 1. If licensees with currently approved Quality Assurance Program Descriptions elect to incorporate the guidance of this SRP revision, it is recommended that NRR accomplish the review and approval as this would represent a major QA program change with potential for unidentified reductions in commitments. | | 1. Staff reviewers will require additional training before reviewing QAPDs to the revised SRP. In addition, NRR staff will be made available to assist regional reviewers as appropriate on a case by case basis. |
| 2. Present NRC inspection modules should be reviewed to assure they encompass the | | 2. Agreed. Although little change is anticipated, a |

| | |
|---|---|
| revised program structure. | review will be made by LPEB after Section 17.3 is issued. |
| General | |
| 1. There are several uses of the word "items" and it is not clear what this word represents, i.e., in some uses it appears that "items" refers to structures, systems, and components; in other uses it appears to refer to material, parts, and components. This is a minor but confusing "item". | 1. "Item" is defined in NQA-1 as "an all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, or unit." We accept this definition. |
| 2. The plan refers to inspections, verifications, and self-assessments. The following questions are not clearly resolved following review of the plan. | 2. See below. |
| a. Is self assessment a generic term or a synonym for audits? (Audits is the Appendix B criterion not directly referenced in SRP Revision 3 but referenced in Revision 2) | a. As stated in II.C.1.a of Section 17.3, the self-assessment function includes safety committee activities, audits, and other independent assessments. |
| b. How do these terms relate to each other and how do they differ? | b. Inspections are one way of performing verifications. NDE is another. Self assessments are as noted in a, above. |
| c. What level of independence is required for each? | c. As stated in II.A.2.b, there is to be independence between persons and organizations executing performance activities and those executing verification and self-assessment activities. The degree of independence may be commensurate with the |

activity's relative importance to safety.

3. The Plan hints at a graded QA approach to quality verification activities. Why not state it, define it, and provide an example?

3. Criterion II of Appendix B states that the QA program shall provide control over activities to an extent consistent with their importance to safety, and this thought is reflected in Section II.A.7.c of SRP 17.3 which refers to Section VI.B. Section VI.B includes references to NRC QA guidance for items that are not safety related. Thus we believe that SRP 17.3 (like Appendix B) requires a graded QA program. SRP 17.3 requires each submitter to define its QA program in response to the acceptance criteria in Section II, and the staff's acceptance of QAPD's using the acceptance criteria will provide the examples as suggested.

Specific

1. II.A.2.b: Performance activities should be clearly defined. Verification activities should be clearly defined. Define the term, "degree of independence." Does this refer to independence from the production task, production group, or functional area?

1. Performance activities are the "doing" functions of designing, purchasing, machining, performing special processes, erecting, operating, maintaining, etc. Verification activities are actions which verify that the doing functions produce acceptable results. NQA-1 defines verification as the act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specified requirements. We accept this definition except that we consider audits to be a self-assessment function. As stated in II.A.2.b, the

| | |
|---|---|
| | "degree of independence" can refer to independence from either the production task, the production group, or the functional area depending upon the activity's importance to safety. |
| 2. II.A.6.e: The term "significant conditions adverse to quality" is not defined. If not defined by the SRP, it should be required to be defined by the QAPD under review. | 2. To my knowledge the NRC has not defined "significant conditions adverse to quality" since it was used in Appendix B. We do not propose to do it in SRP 17.3. |
| 3. II.A.7.b: This section references a limited number of applicable QA Program Regulatory Guides. The statement should reference a more comprehensive list or should be restated as a general reference to applicable QA Program Regulatory Guides. | 3. The Regulatory Guides referenced are the same as those currently referenced except that the ones which currently reference the N-45.2 "daughter" standards have been replaced by referencing NQA-1 and NQA-2. |
| 4. II.B.1.c: The second statement, "Criteria which define acceptable quality are to be specified, and verification is to be against these criteria," is important and should stand on its own rather than be buried in the other important statement requiring use of instructions and procedures for work important to safety. | 4. Agreed. The second statement is now item II.B.1.d. |
| 5. II.B.3.c: Recommend modifying this statement about simulation of the most adverse design conditions for testing of design to say, "simulate as near as practical the most adverse design condition." | 5. SRP 17.3 matches 17.1 and Appendix B in this regard. No change. |
| 6. II.B.3.e: This statement about design verification performance by engineering | 6.This concern is addressed as follows: II.B.3.a requires design verification, II.A.2.b |

supervisor is the first reference to a requirement for design verification by a qualified and independent reviewer. Recommend that a direct statement, requiring a qualified and independent reviewer, occur earlier in this section, i.e., as item 1.

requires verifier independence, and II.A.5 requires trained and qualified verifiers.

7. Section II.B.4, "Procurement Control," does not reflect the Appendix B criterion VII requirement that documentation of material and equipment conformance to procurement requirements be available at the nuclear power plant prior to installation or use of the material or equipment.

7. Part f has been inserted in II.B.4 as follows: "The program is to include provisions for ensuring that documentary evidence that items conform to procurement requirements is on site prior to installation or use of the item."

8. II.B.4.h (now "i"): The requirement for commercial grade items to "perform as designed" is vague. The SRP should state what we expect, i.e., assurance that the item will perform satisfactorily and reliably in the system, structure, or component.

8. ". . . perform as designed" has been changed to ". . . perform satisfactorily in service."

9. II.B.6: "Items" in the title, "Identification and Control of Items," should be replaced with "Materials, Parts, and Components" for clarity and to conform to associated Appendix B criterion category titles.

9. Use of "items" is in accordance with the NQA-1 definition (see the resolution of general comment 1 above).

10. II.B.8.d: Recommend deleting "availability" as this does not appear to have meaning in the context of providing guidance for test performance.

10. "Availability" has been deleted.

11. II.B.9: M&TE is not defined. M&TE should be defined or required to be

11. II.B.9.b requires that the types of equipment covered by the M&TE control program be

| | |
|---|---|
| defined by the QAPD. | defined. Also, NQA-1 has an acceptable definition. |
| 12. II.B.9.g: Requirement for QAPD to address acceptability determination of use of out-of-calibration M&TE does not include reference to timeliness of performance. Recommend that timeliness be addressed. | 12. This would constitute a new requirement. As such, it is not incorporated into Section 17.3. |
| 13. Section II.B.10, "Inspection, Test, and Operating Status," does not have a clear meaning as to what these statements apply. It appeared that condensation of the Appendix B criterion XIV on this subject resulted in some loss of clarity. For example, the item addresses physical identification of items by tagging, marking, etc. to indicate status of tests or inspections of that item. Additionally operating status of structures, systems, and components to indicate operating status or prevent inadvertent operation (i.e. system tag out program) should be with physical identifiers such as tagging or marking, on the item. | 13. Transfer of the SRP 17.1 guidance into SRP 17.3 in this area is shown on pages 10 and 11 of Enclosure 3 of this package. II.B.10.b indicates that the status of items should be verified before use in order to prevent inadvertent operation. A "system tag-out program" would be a new SRP requirement. As such, it is not incorporated into Section 17.3. |
| 14. Section II.B.13, "Corrective Action," does not address timeliness of corrective action or measures to preclude recurrence. These requirements are addressed in Appendix B criterion XVI and SRP revision 2, item 16. | 14. Section II.a.6 requires management's involvement in the corrective action program and requires measures to preclude recurrence of conditions adverse to quality (II.A.6.b). While timeliness of corrective action is not addressed specifically in SRP 17.3, personnel performing the self-assessment function will audit per SA - Assessment "a" to verify acceptable timeliness of corrective action. Auditor independence |

| | |
|---|---|
| | is addressed in I.A.2.b and training in II.A.5. |
| 15. II.C.1.c: How does this criterion, "Personnel performing self-assessment activities are not to have direct responsibilities in the area they are assessing," apply to self-assessment activity within a functional area? For example the engineering organization may have internal self-assessment activities to evaluate the quality of their work product. Recommend defining licensee self-assessment program activity as distinct from internal functional area self-assessment activity. | 15. Self-assessment activities are not to be performed by personnel who are responsible for or who performed the work being assessed. Engineering organizations should evaluate the quality of their work product: but, even in this case, the evaluators should not be evaluating their own work. Supervisors are responsible for the work of their personnel, and audits of this work need to be done by someone other than the supervisor. We believe the acceptance criteria are clear in this regard. |
| Source: H. J. Miller, Director DRS, Region III | (Comments per memo to Roe, 2/28/90) |
| COMMENT | RESOLUTION |
| General. We strongly support the efforts being made to encourage licensees to develop performance-based quality assurance programs. To that end we are pleased that the proposed revision does not require the Quality Assurance organization to perform line activities such as review of procedure revisions, procurement documents, and nonconformance reports on a routine basis, freeing these organizations to perform more technical and performance oriented audits and surveillances. However, we are concerned that the proposed revision utilizes the draft revision of Regulatory Guide 1.33 and correspondingly | General. Section 17.3 does not refer to specific revisions of regulatory guides. Due to the time required to revise regulatory guides (there are drafts of Revision 3 of Regulatory Guide 1.33 dating back more than 10 years), Section 17.3 allows (but does not require) organizations with NRC-approved QAPDs to update them to the latest industry quality assurance standards. Specific Comment 18, below, also addresses this issue. |

deletes reference to all of the regulatory guides superseded by the development of NQA-1 and NQA-2. We consider it essential that the revision to the regulatory guide be completed and issued prior to the issuance of this proposed revision to the Standard Review Plan. Specific comments follow.

1. For clarity, change the 2nd sentence of the 2nd paragraph of Section I, as follows: "Therefore, the applicant must emphasize a philosophy whereby each individual, properly trained and motivated, achieves the highest quality of performance ~~of~~ which he or she is capable."

1. Sentence now reads: "Therefore, the applicant must emphasize a philosophy whereby each individual, properly trained and motivated, achieves the highest quality of performance of which he or she is capable."

2. Section II identifies the following items as acceptance criteria; however, in most cases, the items consist of issues to be addressed by the QAPD. The true acceptance criteria are those contained within the regulatory guides in sections VI.A and VI.B. We suggest that this section be reworded as follows: "Criterion 1 of 10 CFR Part 50, Appendix A, ~~"General Design Criteria for Nuclear Power Plants,"~~ requires that a QA program be established and implemented. Appendix B of 10 CFR Part 50, 'Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,' specifies 18 quality criteria ~~which must be addressed in a QAPD~~. Other than where ~~Except when~~ acceptable alternatives are provided, the specific attributes to be addressed are

2. The acceptance criteria are in the text, and item II.A.7 requires commitment to regulatory guides (or alternatives). Section II now reads: "This section outlines and specifies the NRC's acceptance criteria for QAPDs. Criterion 1 of 10 CFR Part 50, Appendix A, 'General Design Criteria for Nuclear Power Plants,' requires that a QA program be established and implemented. Appendix B of 10 CFR Part 50, 'Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,' specifies 18 quality criteria which must be addressed in a QAPD. Except when acceptable alternatives are provided, the acceptance criteria that follow provide attributes to be addressed for a QAPD to be found acceptable. The QAPD should describe how each of

| | |
|---|---|
| as follows ~~acceptance criteria that follow provide attributes to be addressed for a QAPD to be found acceptable~~. The QAPD should describe how each of these attributes is addressed ~~the acceptance criteria will be met~~. Acceptance criteria for the specific attributes are provided in the appropriate regulatory guides and Branch Technical Positions contained within Sections VI.A and VI.B of this chapter." | the acceptance criteria will be met." |
| 3. Although item II.A.2.e(4) specifies that the performance of delegated work be formally evaluated by the licensee, no frequency is specified. Assuming that this criteria only applies to delegated work (e.g., done by contractors), we recommend that the work be formally evaluated by the applicant on a schedule commensurate with the complexity of the work and its importance to safety. | 3. This is partially covered on a generic basis in item II.A.1.d which states: "The QAPD is to provide measures to ensure the quality of items and activities to an extent consistent with their importance to safety."<br><br>The idea that evaluation scheduling be based on "the complexity of the work" constitutes a new SRP requirement. As such, it is not incorporated into Section 17.3. |
| 4. Item II.A.3.e should be clarified to describe what is meant by the term "necessary means to accomplish their assigned tasks," for example, appropriate equipment, training, and procedures. | 4. "Means" has been changed to "training and resources" in item II.A.3.e to clarify the item and make it consistent with item II.A.3.d. |
| 5. Item II.A.4.b: To ensure independence, we recommend that "responsibility and authority to stop unsatisfactory work and control further processing" be vested in an individual who is independent from cost and schedule considerations such that they (cost and schedule) do not unduly influence | 5. Item II.A.4.b now reads: "Responsibility and authority to stop unsatisfactory work and control further processing, delivery, installation, or use of nonconforming items (such as structures, systems, components, parts, materials, equipment, consumable materials, and software) is to |

| | |
|---|---|
| decision making. | be assigned by the applicant such that cost and schedule considerations do not override safety considerations. |
| 6. Item II.A.5.b: More guidance should be provided on what constitutes an acceptable training program. Specifically, elements from the Commission's Policy Statement on Training and Qualification of Nuclear Power Plant Personnel should be added as follows: "Training programs to ensure that personnel achieve and maintain suitable proficiency are to be established and implemented. Such programs should be based on a systematic approach to training which incorporates the following five elements: (a) systematic analysis of the jobs to be performed; (b) learning objectives derived from the analysis which describe desired performance after training; (c) training design and implementation based on the learning objectives; (d) evaluation of the trainee mastery of the objectives during training; and (e) evaluation and revision of the training based on the performance of trained personnel in the job setting." | 6. The proposed additional requirements are too detailed for the "top-level policy document" that QAPDs are to be. In a letter of 3/9/90 to the chairman of the ASME NQA-1 Programmatic Activities Work Group, we have proposed that these requirements be included in Supplement 2S-4, "Supplementary Requirements for Personnel Indoctrination and Training," of NQA-1. |
| 7. The term "no fault" is utilized in item II.A.6.a. We suggest this sentence be expanded to provide the definition of what is meant by "no fault." | 7. Item II.A.6.a, under the heading "Corrective Action," states: "Plant management, at all levels, is to foster a "no-fault" attitude toward the identification of conditions that are adverse to quality, such as failures, malfunctions, nonconformances, and out-of-control processes including the failure to follow procedures." A "no |

| | |
|---|---|
| | fault" attitude indicates that the purpose of corrective action is not to point fingers but to correct problems. In this context no change is made. |
| 8. Item II.A.6.b: We recommend that the first sentence be modified as follows: "A corrective action program is to be established and implemented that includes prompt identification, documentation, classification, cause analysis, prompt correction of the conditions, elimination of the cause of significant conditions, and follow-up of conditions that are adverse to quality." The addition of the word "prompt" corresponds to the text of the Appendix B requirement. | 8. Appendix B requires measures to assure that conditions adverse to quality "are promptly identified and corrected." Since the documentation, classification cause analysis, etc. are all part of correcting a condition adverse to quality, the first "prompt" has been added, but not the second. |
| 9. We recommend that item II.A.7.e be deleted as it is specifically required by 10 CFR 50.54(a)(3) and 10 CFR 50.55(f)(3). Therefore, requiring its inclusion in the QAPD is redundant. | 9. The 10 CFR references apply to holders of NRC licenses and construction permits only. Item II.A.7.e requires the same updating commitment from others whose QAPDs are reviewed by the NRC. |
| 10. Item II.B.4.g should not be restricted to only repair and replacement parts, but should address all components. We recommend that it be worded as follows: "The procurement of components, including spare and replacement parts, is to be subject to quality and technical requirements suitable for their intended service and to the purchaser's current QA program requirements." | 10. So changed. |
| 11. We recommend that wording from the regulation for design control be incorporated into | 11. So changed. |

item II.b.4.h to make it clearer to the licensee that commercial grade items are subject to the same quality requirements as safety-related items if they are used in safety-related applications. Specifically: "Appropriate controls for the selection, determination of suitability for intended use (critical characteristics), evaluation, receipt, and quality evaluation of commercial-grade items are to be imposed to ensure that they will perform as designed."

12. We recommend that item II.B.7.d be expanded to clarify the source of acceptance criteria, namely: "Acceptance criteria contained in applicable design and procurement documents."

12. Item II.B.7.d now reads: "Items are to be marked and labeled during packaging, shipping, handling, and storage to identify, maintain, and preserve the items' integrity and indicate the need for special controls contained in applicable design and procurement documents."

13. Item II.B.10.b should be expanded to pick up a description of some of the labels listed in the old chapter 17.1, namely: "The application and removal of status indicators and other labels such as inspection or welding stamps are to be controlled."

13. The proposed wording is too detailed for the "top-level policy document" that QAPDs are to be. Note that item II.B.10.b could also pick up some of the status indicators listed in the old Section 17.1 such as tags, markings, labels, and stamps. Item II.B.10.b has not been revised.

14. Item II.B.14.a: We feel that a brief elaboration of what constitutes "documents" in light of the cross reference would be useful. Therefore, we suggest rewording this item as follows: "A program is to be established and implemented to control the development, review, approval, issuance,

14. Examples of "documents" are given in item II.B.14.b, and II.B.14.a has not been revised.

use, and revision of documents, including procedures, procurements, instructions, and drawings.

15. In comparing item II.B.14.b with the associated sections of the current standard review plan, we note that the Topical Reports and Safety Analysis Report have been deleted from the list of examples of documents to be controlled. In addition, discussion of as-built drawings no longer reference the need to actually reflect plant design. In light of industry problems in this regard, we suggest that this item be reworded as follows: "The scope of the document control program is to be defined. Examples of documents to be controlled include design drawings, as-built drawings that accurately reflect the actual plant design, engineering calculations, design specifications, computer codes, purchase orders and related documents, audit and surveillance procedures, operating procedures, emergency operating procedures, technical specifications, nonconformance reports, corrective action reports, work instructions and procedures, calibration procedures, quality verification procedures, ~~and~~ inspection and test procedures and reports, topical reports, and the Safety Analysis Report."

15. Comment incorporated except that "as-built drawings that accurately reflect the actual plant design," as suggested, has been changed to "as-built documents that accurately reflect current (up-to-date) plant design."

16. We recommend clarifying item II.B.15.a to address nonconformance reports, special

16. We have tried to be consistent and use "items" in accordance with the NQA-1

process controls, and controlled documents as follows: "A program is to be established and implemented to ensure that sufficient records of items (such as nonconformances and controlled documents) and activities (such as design, engineering, procurement, manufacturing, construction, special process control, inspection and test [such as manufacturer's, proof, receipt, pre-operational, and post-installation,] installation, pre-operation, start-up, operations, maintenance, modification, decommissioning, and audits) are generated and maintained to reflect completed work."

definition which says an item is an all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, or unit. Therefore, we have not included the first parenthetical expression. Also, we consider special processes to be part of a manufacturing, construction, or inspection operation and have not added "special process control" to the list.

17. We recommend that item II.C.2.e be expanded to address those situations where the QA organization may lack sufficient technical expertise to audit a specific area, specifically: "Scheduling is to be dynamic and resources are to be supplemented when QA program effectiveness is in doubt or appropriate technical expertise is not available."

17. Item II.A.3.d requires that audit personnel are trained and resources are available before an audit is undertaken, and item II.A.5.a requires that audit personnel are capable of performing their audits. These two items satisfy the concern and item II.C.2.e is unchanged.

18. We have two comments regarding Section VI.A:

18. See below.

a. We do not feel that this section should delete mention of the regulatory requirements related to quality activities, namely Part 50 Appendix A criterion I; Part 50, Appendix B, all parts; 50.34(a)(7); 50.54(a), all parts; 50.55(a); and 50.55(e).

a. All activities of Part 50 are "quality activities." Therefore it would not be appropriate to single out only specific parts and list them in Section VI.A.

| | | |
|---|---|---|
| b. | We note that the references are based on a revised Regulatory Guide 1.33 having been issued which endorses NQA-1, NQA-2, and ANS 3.2. In this case, we strongly recommend that the issuance of this standard review plan be delayed until the formal issuance of the revised regulatory guide 1.33. In addition, we recommend that all of the superseded regulatory guides (1.30, 1.37, 1.38, 1.58, 1.64, 1.74, 1.88, 1.94, 1.116, 1.123, 1.144, and 1.146) be deleted, and regulatory guide 1.33 clearly indicate how those regulatory guides have been incorporated into 1.33. | b. Item VI.B.5 references: "Regulatory Guide 1.33, 'Quality Assurance Program Requirements (Operations),' with appropriate substitution of NQA-1 and NQA-2 for N-45.2 and its daughter standards," and it is neither required or desirable that the issuance of SRP Section 17.3 be delayed. The regulatory guides listed to be deleted cannot be deleted as long as there are plants in existence whose NRC accepted QAPD commits to these older guides. To require an update would be a backfit which could not be justified. Therefore, the proposed forward-fit of SRP 17.3, allowing applicants to update their quality assurance programs to meet SRP 17.3 if they desire to do so, is the thing to do. |
| **Source:** | L. J. Callan, Director DRS, Region IV | (Comments per memo to Spraul, 3/2/90) |
| COMMENT | | RESOLUTION |
| 1. | We concur that the proposed revision eliminates the current fragmentation of the self-assessment responsibilities and simplifies the format. | 1. None required |
| 2. | We note that the proposed revision permits a significant departure from typical organizational structure and practices that have been used in implementing the quality assurance function. While we do not have a problem with the | 2. The acceptance criteria are clearly defined in Section 17.3 of the SRP. However, with the criteria being less prescriptive and directed more to the applicants' goals and objectives, we agree that staff reviewers will require |

overall thrust of the revision, our perception from reading the SRP is that implementation of this approach could lead to potential problems in the absence of additional staff actions. In particular, the de-emphasis on clearly defined acceptance criteria for a quality assurance program could, in our view, lead to staff acceptance of a less than satisfactory program.

additional training before reviewing QAPDs to the revised SRP. In addition, NRR staff will be made available to assist regional reviewers as appropriate on a case by case basis.

3. Similarly, we believe that issuance of detailed NRC inspection guidance in this area would be warranted should utilities opt to adopt this approach to the quality assurance function.

3. Detailed guidance will be provided with the training of reviewers as noted above.

**Source:** R. Zimmerman, Director DRSP, Region V

(Comments per memo to Roe, 3/5/90)

COMMENTS

1. We agree with the change of focus to place the QA organization in the more appropriate role of assessing the quality of work activities, in lieu of the current practice of QA providing assurance through in-process verifications of work activities. This approach, which relies more heavily on line management to be responsible for implementing the QA program, should improve the overall performance of work activities affecting plant safety. It is most appropriate that the QA organization shift emphasis to concentrating on rooting out problem areas, rather than merely verifying the quality of in-process work.

RESOLUTION

1. None required.

**Source:** O. P. Gormley, ARGIB/DRA/RES

(Comments per memo to Spraul, 3/19/90)

| COMMENT | RESOLUTION |
|---|---|
| General | |
| 1. I understand that Chapter 17.3 will replace Chapters 17.1 and 17.2. If that's the case, does that mean that secondary responsibilities will be eliminated? I guess you've already determined how they feel about that. What about the inspection organization? It seems as if they would have some important perspectives to offer. It looks to me that some of the changes proposed might be difficult to inspect and enforce. If it replaces 17.1 and 17.2, why isn't it simply Chapter 17? | 1. The acceptance criteria no longer require that the QAPD includes a list of items subject to the QA program: rather, criteria used to identify the items and activities to which the QA program applies are to be in the QAPD (see II.A.1.c). This has eliminated the need of secondary review. Comments on 17.3 have been requested and received from involved NRC organizations and incorporated as indicated herein. Since 17.3 is not a backfit, 17.1 and 17.2 remain viable for existing QAPDs. |
| 2. What do you intend for the purpose of the Chapter? I had the impression that guidance to the applicant would be through the reg. guides endorsing industry standards, and guidance to the internal NRC reviewers would be through the SRP. Then the SRP would be a check list based on the reg guides and the standards they endorse. As I read Chapter 17.3, there seems to be inconsistencies between the guidance given to the applicants, and the guidance given to the NRC reviewer. In some instances "requirements" seem to be relaxed and in others new requirements appear. Won't this lead to confusion in the industry? Did you pick up all the generic letters and | 2. The principal purpose of SRP 17.3 is to ensure the quality and uniformity of staff reviews of QAPDs. It is also a purpose of SRP 17.3 to make information about regulatory QA matters widely available and to improve communication and understanding of the staff QA review process by interested members of the public and the nuclear power industry. The SRP provides guidance, not requirements, and the guidance in 17.3 is given for both the applicant and the reviewer. Thus there can be no inconsistency. The disposition of each acceptance criterion of 17.1 and 17.2 is shown in Enclosure 2, and we believe that industry is capable of understanding 17.3. |

bulletins, either in the text, or certainly in the references? I didn't see any. They are a really difficult item to deal with when trying to revise regulatory guides.

We have not attempted to include all the generic letters and bulletins, but Generic Letter 89-02 has been added to Section VI.B per the suggestion of DRIS.

3. Perhaps I'm reading it wrong, but I think I detect a trend away from following procedures, and away from the use of independent quality assurance organizations and professional quality assurance people. The strict adherence to procedures is what you use not only to achieve quality, but to keep yourself out of serious trouble. In other words, the end doesn't justify the means. It's <u>not</u> O.K. to change the current setting on your welding machine as long as the part appears to be stuck together when you're done. What about specialized quality skills like auditing and the ability to spot a deficiency and track it down to its source? Aren't those skills needed by the self-assessment people?

3. II.A.3.f states that procedures are to reflect the QA policy, and work is to be accomplished in accordance with the procedures. Thus there is no trend away from following procedures. Independence of both verifiers and personnel performing the self-assessment function is specified in II.A.2.b, and people are to be trained and capable of performing their assigned tasks per II.A.5. However, as noted in the comment, there is no requirement for an "independent quality assurance organization." Although the guidance of 17.1 and 17.2 ofttimes refers to a "QA organization," such an organization is not a requirement of Appendix B. SRP 17.3 reflects the statement in Appendix B that states: "the organizational structure for executing the quality assurance program may take various forms provided that the persons and organizations assigned the quality assurance function have this required authority and organizational freedom." (That is, to identify quality problems; to initiate, recommend, or provide solutions; to verify implementation of solutions; and to have sufficient independence from cost and schedule when opposed to safety considerations.)

4. Some of the guidance doesn't lend itself to use by reviewers. It seems to be more oriented to exhorting some response from the applicants. I have some more appropriate examples later, but the third paragraph on the first page under Areas of Review illustrates the point when it says, "Therefore the applicant must emphasize a philosophy whereby each individual, properly trained and motivated, achieves the highest quality performance of which he or she is capable. This emphasis on individual performance reinforces the importance of the self-assessment process, the object of which is to independently review and evaluate overall performance." Now, if I were a reviewer trying to judge an applicant's program submittal, I'd have a hard time with that one. I think that these areas which are subjective rather than objective, are a significant shortcoming of the Chapter. That isn't to say that we don't need to do something about licensee's emphasis on documentation vs. performance. I just don't see how it can be done this way.

4. The quoted words are to set the tone of the applicant's quality assurance program. In light of this comment (and others in this area), the quoted words have been changed to: "Therefore, the applicant must develop and maintain ~~emphasize~~ a philosophy whereby each individual, properly trained and motivated, achieves the highest quality of performance of which he or she is capable. This emphasis on individual performance reinforces the importance of the self-assessment process, the object of which is to independently review and evaluate overall performance." However, the reviewers will not use these words to determine the acceptability of a QAPD. As indicated in the opening paragraph of Part II, "Acceptance Criteria," the reviewers will be using the more objective acceptance criteria given in Part II of SRP 17.3.

5. In spite of the above, I believe the Chapter opens up some areas which need to be addressed and makes some necessary improvements. One is procurement, and another is management involvement and responsibility. I wonder if this is the appropriate way to tighten these requirements and to make new ones, though. Shouldn't we first try to get

5. There is no tightening of requirements nor are there new requirements. The requirements are in Appendix B, and the SRP provides guidance, not requirements. While the guidance in SRP 17.3 may be somewhat less prescriptive than that provided in 17.1 and 17.2, it does not represent any new staff positions. The cover

| | |
|---|---|
| the consensus standards folks to make the improvements and then endorse the standards, or put the requirements in the reg guides if that doesn't work. | letter identifies three things that it does, and the resolution of Region III's general comment addresses the updating of Regulatory Guides. |
| 6. If this is a good time to revise the SRP, maybe we should also see what additional requirements are needed to accommodate the combined licensing requirements of proposed Part 52. | 6. We do not propose to add new "requirements" (guidance) to the SRP at this time. |
| Specific | |
| 1. With the 18 Criteria of Appendix B being the governing requirements and with the industry consensus standards on which the licensees build their programs all being structured on the 18 criteria, the format change in Chapter 17 which now obscures them could be a problem for reviewers. I think a Matrix which helps the reviewers relate the licensee's submittals to the SRP should be a part of the Chapter. | 1. As submittals are made to meet SRP 17.3, the reviewer has the option of requesting that the applicant supply any matrices that may be required. We do not think it advisable to add a matrix to SRP 17.3. |
| 2. II A.2.b: By lumping folks performing verification activities in with those performing the self-assessment ones, you seem to be implying a greater degree of organizational independence for the former than has been the case in the past. For example folks doing the verification of engineering activities usually report to another group, but perhaps to the same manager as the supervisor of the group performing the work, and well below the engineering manager. | 2. See the response to General item 3 above regarding organization arrangements and the independence of verifiers and personnel performing the self-assessment functions. |

On the other hand the QA department is usually totally separate and reports at a vice presidential level. Am I reading too much into that?

3. II.A.2.d: There's an english glitch in the third line which will cause folks to look for the wrong thing there. The items listed are not characteristics of the person, nor are they qualifications. They are features of the position.

3. Clarified as follows: The person filling this position is to:

(1) Have sufficient authority . . . .
(2) Report at a management level . . . .
(3) Have effective lines of communication . . . .
(4) Have no unrelated duties . . . .

4. II.A.3.d&f: What are we looking for here - just a commitment to do these things? In (f), I assume you mean that the manager responsible for performing a task subject to QA will approve the procedures for performing not only the work, but also the applicable QA procedures. I assume you also mean him to be responsible for implementing the QA procedures. If that's the case, doesn't it get us back to the old QC/QA argument, and raise the question of independence? I don't have any quarrel with the manager of projects signing off on QA procedures to be applied by your self-assessment people, but the quality work he does, and is responsible for, has always been called QC. QA used to mean the independent assessment by the special group.

4. In response to II.A.3.d, we would accept a commitment that, before an activity within the scope of the QA program is undertaken, the applicant will ensure that the applicable portions of the QA program is properly documented, approved, and implemented (people trained and resources available). II.a.3.f seems self explanatory. Since the applicant is responsible to describe its organization for achieving and ensuring quality, we do not visualize the old QC/QA organization argument reappearing. As noted earlier, independence of the verifier from the doer is required with the amount of independence being a function of the safety importance of the activity or item whose quality is being verified.

5. II.A.6.b: If we are going to increase requirements this way, I would have expected a stronger position

5. II.A.6.b is not an increase of requirements. Rather, it incorporates the guidance of all or part of

on corrective action. This is an area where NQA hasn't been overly cooperative. I expected to see the phrase "root cause analysis." I also expected to see a section which addressed your excellent comment on the recent NQA ballot, about getting to the basic underlying cause vs.the apparent cause. I'd give you some words, but they are difficult to write without getting into the problem of exhorting performance from the licensee vs. telling the reviewer what to look for.

acceptance criteria 15.1(1), 15.4, 16.1(1), 16.2, 16.3, and 16.4 from SRP 17.2 into this one criterion of SRP 17.3. Since we are not increasing "requirements," we are not addressing root cause analysis in more detail than it is currently addressed in SER 17.2.

6. II.B.1: I have difficulty with the concept of "acceptable quality" in a regulatory environment; especially in verifying it and establishing criteria which define it. Perhaps you don't, and, after I see how it is further defined and implemented, maybe I won't either. However, if one defines quality as that an item performs as intended, then in a highly controlled endeavor such as a nuclear power plant, all one can achieve is that he did what he was supposed to do, according to the instructions (procedures) he was given, and the verifier can only verify that the job was done according to instructions. Even in an engineering environment where there is more freedom (and where we compensate for that by requiring independent verification), there are controls on the tools and methods. I can understand how we want the licensee to make the workers and verifiers

6. The response to the questions, "Who can we hold accountable?" and "How can we enforce what you have here?" is that the new SRP 17.3 does not change anything in this regard. Enforcement action will continue as in the past unless changes to other documents change the enforcement policy and procedures. The meaning of the expressions, "acceptable quality" and "criteria that define acceptable quality," depends upon the item or activity that the expression applies to. For example, a piece of hardware is of "acceptable quality" if it meets the design requirements. The design requirements are of "acceptable quality" if the hardware that meets the design requirements will perform satisfactorily in service. Operational activities are of "acceptable quality" if they are performed in accordance with procedures. Procedures are of "acceptable quality" if they give the desired results. And so on. But 17.3 is no

responsible, but who can we hold accountable? The proposed wrongdoing rule only covers deliberate wrongdoing. How can we enforce what you have here?

"Criteria that define acceptable quality" is even a more difficult problem. Usually all we can hope for is to achieve some level of assurance of quality which is based on assembled evidence that all the controlled actions designed to produce quality have been taken.

different from 17.1 and 17.2 in this regard. No change has been made to the SRP.

7. II.B.2.b: Did you want to introduce the idea of requiring a configuration management program?

7. No. One policy in the development of SER 17.3 is that no new acceptance criteria be introduced.

8. II.B.2.f: I don't think that regulators ought to require that changes be justified. I think we can only require that the changes preserve the ability of the item to perform as intended. A configuration management program would provide some level of assurance that all requirements and interfaces are evaluated.

8. Agreed. The criterion has been revised to delete the need for justification. As noted above, a configuration management program is not specified.

9. II.B.2.g: I think that interfaces should be controlled as well as defined.

9. Agreed. "Interface controls" in 17.1 was changed to "Interfaces" in 17.3. The criteria has been revised appropriately.

10. II.B.3.d: This could use some clarification with respect to "independently verified" and "other organizations." From context, I took it to mean that we would prefer that they give up the practice of building the plant from draft drawings etc.

10. The criterion has been clarified as follows: "Independent design verification is to be completed before design outputs are used . . . ."

I first interpreted it to mean that the A-E couldn't use the licensee's as built drawings, a constructor couldn't use the A-E's drawings or that the A-E couldn't use the NSSS's dose rates without doing an independent verification. You don't mean that, do you?

11. II.B.3.e: I like the NQA-1 circumstances better - they're more restrictive. Chapter 17.1 [3E4(3)] requires QA audits to guard against abuse. I guess I think that specifying QA responsibility might cut down on abuse vs. not specifying anyone as in Chapter 17.3.

11. SRP 17.3 requires an independent verification to guard against abuse. As with all other independent verifications, it is the responsibility of the applicant's management to assign the responsibility.

12. II.B.4&5: Did I miss something in GL 89-02, or is procurement verification an important new requirement being added here? Verification, as I understand it, and as used in other parts of the chapter, means a lot more than audit. Also, <u>verification of quality</u> is a lot more difficult than verification of supplier's activities ala 17.1, II-7A2. I agree that something like this is needed somewhere, but I think some more explanation is needed too. For example, who will do the verification? Is there a place for audits in the policy?

12. The heading of II.B.5 is new. The concept and the acceptance criteria are not. In Section 17.1, acceptance criterion 7.A.2 requires audits, surveillance, and inspections to assure supplier compliance with quality requirements. In Section 17.3, this is called "procurement verification." Again, it is the responsibility of the applicant's management to assign responsibilities. Audits are part of the self-assessment activity of II.C in Section 17.3.

13. II.B.8.a: This should probably have an "as appropriate." Not all items will need to be tested. Also, there should be a requirement to ensure that testing can be and will be conducted in such a way that the plant will be protected. ie. can be kept out

13. Virtually all of the acceptance criteria could have an "as appropriate" since few criteria apply 100% of the time. The suggestion regarding the protection of the plant would constitute a new requirement. As such, it

of unanalyzed conditions or physically detrimental conditions like over pressure of mating systems during hydro test, exceeding allowable pressures at low temperatures.

is not incorporated in Section 17.3.

14. II.B.11: I'd like to see forging, casting, terminating and splicing added to the list of special processes to raise consciousness in those often forgotten areas.

14. The examples of special processes are those from Section 17.1. Additions to the list could be construed as an increase in requirements. Therefore, no change is made.

15. II.B.13: The aggregate of this and II.A.6 still falls short of what is needed with respect to tracking, identifying root causes and correcting the root causes. Will we be looking to NQA-1 for additional requirements on corrective action? Para II.B.13.a is a good idea,but it is more of an employee suggestion program. As you know the corrective action program is to track down and resolve deficiencies which have resulted in a deficiency. It's not voluntary, and doesn't require someone to spot a problem. Therefore it's enforceable. While II.B.13.a is an excellent idea and a good objective, and probably should be included in something, it seems to be unenforceable.

15. II.B.13 & II.A.6 respectively address corrective action from a performer/verifier perspective and from a manager perspective. Collectively, these two parts of Section 17.3 include the collective action guidance provided in Section 17.1. Therefore, they fall short of what is needed to the same extent as the prior guidance. NQA-1 would indeed be a good place to put addition guidance concerning corrective action. The responsibilities of Item II.B.13.a, that were assigned to persons and organizations performing the QA function (per Section 17.1), are no longer so limited.

16. Here are some examples of "requirements" which struck me as being too subjective to allow the reviewer to make a reasonable evaluation, and being too vague to allow enforcement.

16. See below.

a. Pg 1 I already pointed out the problem with emphasizing a philosophy.

a. This comment is addressed in the resolution of general comment 4, above.

| | | |
|---|---|---|
| b. | II.A.3.e: "Individual managers are to ensure that personnel . . . are provided the necessary means to accomplish their assigned tasks." | b. The QAPD should include such a commitment or an acceptable alternative. Note that "means" has been changed to "training and resources." |
| c. | II.A.6.a: "Plant management . . . is to foster a 'no-fault' attitude toward identification of conditions adverse to quality . . . ." | c. The QAPD should include such a commitment or an acceptable alternative. |
| d. | II.B.1.a: "Personnel performing work activities . . . are responsible for achieving acceptable quality." | d. The QAPD should include such a commitment or an acceptable alternative. |
| e. | II.B.1.b: "Personnel performing verification activities are responsible for verifying the achievement of acceptable quality." | e. The QAPD should include such a commitment or an acceptable alternative. |
| f. | II.B.2.c: "Design inputs are to be correctly translated into design outputs . . . ." (What we usually do to achieve something like this is to provide a verification step.) | f. The QAPD should include such a commitment or an acceptable alternative. |
| g. | II.B.5.b: "As necessary, this (the procurement verification program) may require verification of activities of suppliers below the first tier." | g. The QAPD should include such a commitment or an acceptable alternative. |
| h. | II.C.1.a: "Personnel responsible for the self-assessment function . . . are to be cognizant of day-to-day activities so that they can act in a | h. The QAPD should include such a commitment or an acceptable alternative. |

| | | |
|---|---|---|
| | management advisory function." | |
| i. | II.C.1.b: "Organizations performing self-assessment activities are to be technically and performance oriented, with their primary focus on the quality of the end product and a secondary focus on procedures and processes. | i. The QAPD should include such a commitment or an acceptable alternative. |

not being deleted.) We do intend, however, to permit current licensees to adopt Section 17.3 if they choose to do so.

The proposed revision to the SRP is a Type I revision, as defined in NRR Office Letter No. 800. The format of Section 17.3 is substantially different from that of Sections 17.1 and 17.2. However, it neither incorporates new or revised requirements nor substantively changes the existing guidance. Therefore, we do not believe it is necessary to issue it for public comment.

Enclosures 2 and 3 are provided to assist your review. Enclosure 2 lists each element of Sections 17.1 and 17.2 of the Standard Review Plan and indicates where the element is reflected in Section 17.3. Enclosure 2 also shows the disposition of those elements which no longer specifically appear. Enclosure 3 includes Sections 17.1 and 17.2 of the present Standard Review Plan.

Any questions you or your staff may have may be directed to Eileen McKenna (X-21010) or Jack Spraul (X-21023).

Original signed by:

Frank J. Miraglia, Jr., Deputy Director
Office of Nuclear Reactor Regulation

Enclosures: As Stated

cc w/enclosures: CRGR (20)
ACRS (15)

cc w/o enclosures:

| | | | |
|---|---|---|---|
| J. G. Partlow | E. J. Butcher | O. P. Gormley | ADT DDs |
| M. W. Peranich | G. R. Klingler | W. S. Schwink | OPGormley |

| | | | |
|---|---|---|---|
| DISTRIBUTION: | AI#180 | | |
| Central File | LPEB Reading | FJMiraglia | WTRussell |
| JWRoe | COThomas | ATGody | GEGrant |
| WHBateman | EMMcKenna | JGSpraul | |

| OFC: | PQEB:DLPQ | PQEB:DLPQ | C:PQEB:DLPQ | DD:DLPQ:NRR | D:DLPQ:NRR |
|---|---|---|---|---|---|
| NAME: | JGSpraul | EMMcKenna | ATGody | COThomas | JWRoe |
| DATE: | 4/27/90 | 4/27/90 | 5/3/90 | 5/3 /90 | 5/ /90 |

| OFC: | NRR:ADT | DD:NRR |
|---|---|---|
| NAME: | WTRUSSELL | FJMiraglia |
| DATE: | 5/4/90 | 5/ /90 |

OFFICIAL RECORD COPY